COLLABORATION MANUAL

The operational framework for the research & innovation collaboration platform

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Baltic Fracture Competence Centre

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BFCC—BALTIC FRACTURE COMPETENCE CENTRE

The Baltic Fracture Competence Centre (BFCC) is a pan-Baltic fracture cooperation network fostering innovation within fracture management. The project consortium consists of a transnational cross-sector partnership involving five hospitals, three companies from the medical technology industry, a university, three clusters and one technology transfer organization.

Due to an ageing society, the need for innovative products and clinical procedures for fracture treatment is increasing as a response to age-related fractures and co-morbidities such as osteoporosis, infections and non-unions. Innovations in fracture management must reduce the cost of care or clearly improve quality of care.

Clinicians will support the innovation process by identifying the clinical needs to ensure user-oriented product development. The collaboration between hospitals across countries will foster the innovation of clinical procedures through the exchange of best practice in fracture management influenced by different national, organizational and regulatory conditions.

However, clinicians and companies often lack insight information about total cost and effectiveness of fracture management and causes of adverse health outcomes in the hospitals. To overcome this information gap, the BFCC will develop and implement a transnational fracture registry with five hospitals from Estonia, Germany, Lithuania, Poland, and Sweden, respectively, providing evidence about fracture treatment in the clinical »real world« and reveal clinical needs as well as potentials for innovation.

The BFCC will publish two innovation reports. The Innovation Report No 1 deals with trends in the surgical treatment methods of proximal femur fractures. The Innovation Report No 2 based on results and findings from registry data analysis will identify innovation needs and potentials.

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1. MANAGEMENT SUMMARY

This document describes the operational framework for the research and innovation (R&I) collaboration platform of the Baltic Fracture Competence Centre (BFCC). The collaboration platform consists of three components, firstly the data transfer (registry), secondly the knowledge transfer and thirdly the network and stakeholder cooperation. In order to find out the different requirements of the stakeholders in fracture management, these were analysed and their different needs assigned to the individual components of the collaboration platform. On the basis of this analysis, it is very easy to deduce what should be considered in future fracture management, e.g. to achieve an efficient and satisfactory cooperation of different stakeholders.

The current situation of cooperation between industry and hospitals in five different countries of the Baltic Sea Region (BSR) will be outlined in this document. It reveals which different organisational and regulatory framework conditions influence the cooperation. Directly from the BFCC project, especially from the three demonstration pilots, insights regarding the communication between the partners are integrated and challenges that companies and hospitals have to face in order to successfully and jointly achieve the set goals are addressed.

The procedure for stakeholders from the BSR, who are interested in working with the BFCC, whether to enter data into the registry themselves or to obtain data / evaluations from the registry or to know how they can use the BFCC collaboration platform (data transfer, knowledge transfer, network & collaboration) will be explained and every interested stakeholder learns how to obtain information from the research and innovation network within fracture management.

2. BFCC PROJECT

The BFCC is a joint project of hospitals, industry, research institutions and health/Life Science clusters in the BSR. The BFCC develops and implements a Transnational Fracture Registry Platform (TFRP) of five hospitals from Germany, Lithuania, Poland, Estonia and Sweden, allowing a comparison of the process and outcome quality across institutions and countries. This transnational R&I infrastructure fosters the evidence-based identification of clinical best-practice and needs for innovation. Moreover, BFCC establishes a transnational collaboration platform between hospitals and industry, which will be tested in three transnational pilots, with five hospitals and three companies involved. As part of the EUSBSR flagship project HealthRegion, the project opens the R&I infrastructure and identified innovation needs to all BSR companies.

In the context of this document, the collaboration platform is understood as competence centre combining the three elements data transfer (registry), knowledge transfer (e.g. website, education) and network and collaboration:

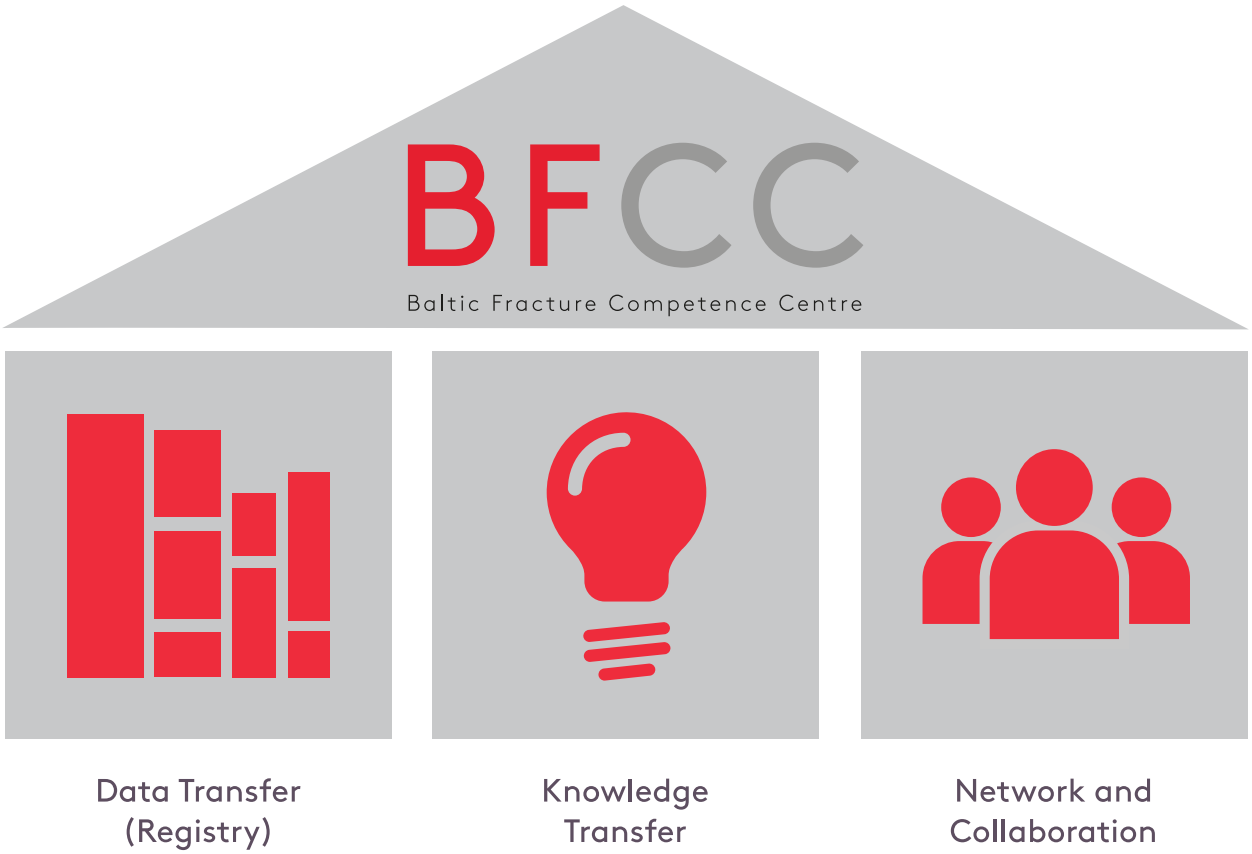

Figure 1: BFCC structure of the collaboration platform

3. STAKEHOLDER ANALYSIS

3.1. Introduction

As part of the Collaboration manual, this chapter introduces a description and needs assessment of all relevant stakeholders in the broader scope of the BFCC project. These have been identified as:

- Physicians
- Researchers
- Hospital management
- Industry
- Local governments
- National governments / European Union (EU)

The following set of needs applies to all stakeholder groups and has been considered during all stages of the project:

- Language barriers — not everybody speaks English well enough to be able to participate and benefit from the tool and platform to its and their fullest potential. This poses a limit on the BFCC's efficacy and output.
- Very different data sets might be useful for physicians, researchers and industry.
- Promotion material must be target group-specific.

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3.2. Physicians

3.2.1. Description

The stakeholder group of physicians which is relevant for BFCC, consists of doctors examining and treating patients experiencing bone fractures or suffering from other bone diseases. They work in hospitals throughout the BSR. Many other physicians in the region work in smaller medical centres or offer services in their own doctor's offices, these are, as of now, not participating in the BFCC. This can be explained by the fact that the registry needs large amount of data to be profitable, and hospitals with many patients are typically able to produce more data in a smaller timeframe. In addition, larger clinics are typically able to allocate more resources and, therefore, possess more possibilities to implement such a new project. In the near future, it should be however considered to include also specialist physicians working in smaller medical centres in the collaboration network, as their insights and expertise would provide an added value to the knowledge transfer component of BFCC, and expands the reach of the project.

Many clinicians are working long hours and carry a lot of responsibility for many patients at the same time. This makes their everyday life extremely demanding and leaves little capacities for further engagement, unless it comes at the cost of other activities.

However, this stakeholder group usually has a high intrinsic motivation for their special field of expertise. This is also needed, and should be ensured by facilitated framework conditions for BFCC participation, e.g. being member of the network, entering data and generally using the data provided by the tool.

The stakeholder group's main interests include:

- Providing quality healthcare in an efficient manner
- Identifying the best possible treatment for patients with a high accuracy rate of the diagnosis
- Spending less time per patient and case, especially for ›ordinary‹ ones
- Seeking possibilities for further training and professional development to increase qualifications and quality of work and treatment outcome
- Seeking networking opportunities for knowledge exchange
- Using state-of-the-art appliances and treatment methods and actively contributing to better treatment outcomes, e.g. through participating in clinical studies, experience exchange in associations, dialogue with industry

3.2.2. Needs

REGISTRY	KNOWLEDGE TRANSFER	COLLABORATION AND NETWORK
Physicians as registry users • A reliable and interactive »Encyclopaedia« of bone fractures and treatment data with a helpful search function and image material (if applicable) • A large amount of data is needed to provide for the full functionality of the tool. But: The larger the individual dataset, the more mistakes will occur (which lead to decreased data quality) and the less likely physicians are to be persistent in filling out all fields for each patient • Possibility to identify or contact the author of specific entries in case of further inquiries	• A handy opportunity for knowledge management and knowledge transfer for all types of bone injury / diseases, possible complications and treatment methods • Well-structured and easily accessible information, e.g. on website • Exchange of best practices and experiences with other physicians, hospital managers, researchers and industry from the BSR	• Facilitation of collaboration with industry and researchers with a clearly defined scope and designated roles and responsibilities • Exchange of best practices and experiences with other physicians, hospital managers, researchers and industry from the BSR • A similar level of expertise in the group (on a certain topic) to allow effective discussions
Physicians as data suppliers • A positive cost / benefit situation → The usefulness and functionality of the tool (see ›physicians as user of the registry‹) must outweigh the amount of time or resources spent to get familiar with the tool and the time needed to enter/maintain data in it • Possibility for cross-linking between different registries used at their hospital and in their region to save time and get the full picture of a case • Guidelines for using the registry (FAQ) • Guidelines for data protection of patients		

Table 1: Physicians' needs

3.3. Researchers

3.3.1. Description

Researchers are typically either situated in universities within the BSR, in public research institutions, or are employed in the private sector, such as in pharmaceutical and health companies (e.g. medical technology). They carry out research, mainly in laboratories and through computer analysis with the help of patient data. Their scientific research helps to understand the background of certain diseases. This knowledge can then be used for the development of new treatment methods, drugs and devices, and the optimisation of existing ones. In the best case scenario, the research leads to insights which allow the prevention of such diseases from occurring in the first place. Researchers do not specifically need to work on bones; indeed research from various dimensions and sub-fields of medicine, pharmaceutics, biology, physics and chemistry might come to produce valuable insights for physicians and industry. Besides carrying out the research itself, many researchers spend a large amount of time and resources on disseminating the results of their work. While possessing great scientific expertise, researchers are not always familiar with the circumstances of practical application of healthcare in the hospitals.

The stakeholder group's main interests include:

- Receiving funding and being paid for their work
- Having a scientific impact by their work
- Receiving scientific recognition
- Publishing in renowned scientific journals or other publications

3.3.2. Needs

REGISTRY	KNOWLEDGE TRANSFER	COLLABORATION AND NETWORK
• A source for clinical information which can be easily accessed • A great amount of available data of high data quality • An automatic data analysis for quantitative, statistical evaluations (saving time for manual study), yet the possibility for gaining qualitative insights through the study of specific cases • Need for detailed information, demonstrated utility and sophisticated analysis in order to be able to trust BFCC as scientific source • Categorical search parameter (good search tool required) for individual data search • Cross-linking possibilities between different registries to get the full picture	• Facilitation of access to sources and target groups of research results • Exchange of experiences and research results with hospitals, physicians and industry representatives	• A platform for collaboration with hospitals, physicians and industry with a clearly defined scope and designated roles and responsibilities • Facilitation of access to new research fields, or rather fields of interest through scientific exchange • Contact possibilities to potential funding sources, e.g. companies, for R&I projects • Contact possibilities to potential customers for research results, e.g. — with regard to reports — patents

Table 2: Researchers' needs


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3.4. Hospital management

3.4.1. Description

The hospitals participating in BFCC are larger hospitals, many being also classified as ›research hospitals‹ and linked to a university. Their management typically consists of both administration personnel and medical staff. They try to keep the hospital functional and profitable, and ensure a good standard in health care for the local population. The hospital management is responsible both for the internal organisation of the hospital as well as for cooperation with third parties. In their function, they are very dependent on the strategic objectives of national and EU policy decisions in the area of public health, as well as on the technical provisions issued by regulatory authorities. Financially, they often rely on payers (e.g. health insurances), the state (allocation of a portion of the government budget created by taxes, in line with their national health care policy) and other third party funds such as project-related funding.

The stakeholder group's main interests include:

- Ensuring a problem-free, smooth and efficient everyday business and patient experience
- Avoid mistakes resulting in compensation fees and longer periods of hospitalisation of patients, thus implying higher costs
- Ensuring a good working environment in order to attract qualified staff that achieves satisfying results while making little mistakes
- Attract many, but not too many patients
- Boosting their own existence and their own business through success stories and good ratings which allows them to receive funds
- Boosting their visibility through collaboration with EU projects and other important players
- Improving their reputation, coming to be known as specialist hospital for bone injuries and diseases
- Landing ›good deals‹ with industry partners which allow for state-of-the-art appliances and treatment methods at affordable costs

3.4.2. Needs

REGISTRY	KNOWLEDGE TRANSFER	COLLABORATION AND NETWORK
• The assurance that BFCC / registry is on the positive side of a cost / benefit analysis — it cannot take up too much time and resources in the busy schedules of a region's leading hospital, e.g. facilitation of data transfer through interface among BFCC and hospital information system • In the best possible scenario, the BFCC would finance the human resources required to carry out data sampling and maintenance of the data in the tool • Quality control ensuring the accuracy and reliability of the data gaining valuable input for the hospital's quality management system (for quality increase and cost efficiency) • Instructions on the technical operation of the registry and how to disseminate the software to the relevant physicians, support in organisational, administrative and training issues → the least possible efforts at hospital side	• Information about the BFCC and the registry • Possibility for affordable further education / specialisation of staff • Receiving performance reports including data of other institutions for comparison • Exchanging best practices and experiences with other hospital managements (learning from each other)	• A platform for collaboration with industry, researchers and authorities with a clearly defined scope and designated roles and responsibilities • Possibility of spill-over effect and more (trans-border) cooperation with other hospitals also on other matters, which can lower costs and increase quality and effectiveness of care • Possibility of spill-over effect and more (trans-border) cooperation with industry also on other matters • Facilitation of contacts to possible employees • Possibility for hospital presentation as site of interest for collaboration and as employer

Table 3: Hospital managements' needs

3.5. Industry

3.5.1. Description

This stakeholder group has very diverse characteristics. The industrial stakeholders involved in BFCC can range from specialised small and medium-sized enterprises (SME), to start-ups still establishing themselves on the market and big corporations which offer a broad service and product portfolio. Some industrial actors are active in the whole EU or BSR, while others operate mainly domestically and on a much smaller and more specialised scale. Companies are typically active in one of these dimensions: software/IT, medical technology, biotechnology, pharma and other related fields.

The stakeholder group's main interests include:

- Making profit, increasing turnover
- Having access to an as-large-as possible global/European market (especially if providing specialised products)
- Gaining access to regulated health markets in the BSR
- Establishing or maintaining themselves on this market and providing a product with continuous demand to ensure reliable cash flow
- Strengthening the position on the market through innovation
- Easily bringing new products to the market

3.5.2. Needs

REGISTRY	KNOWLEDGE TRANSFER	COLLABORATION AND NETWORK
• Being included with own products in the registry's dataset • Facilitation of access to high quality real-life data for better cost-benefit ration of R&D processes and assessment of own products' efficacy • Gaining specific insights in their products' use, complications, and needs for improvement • Possibility to compare own products with others • Possibility to quickly and accurately identify potential for innovation • Facilitation of meeting regulatory framework conditions, e.g. Medical Device Regulation (MDR)	• Access to innovation dialogue activities with hospitals, physicians, researchers and industry representatives • Access to collected information on performance, safety and suitability of several industrial treatment processes for better collaboration and post market surveillance	• A platform for collaboration with hospitals, physicians and researchers with a clearly defined scope and designated roles and responsibilities • Facilitation of cooperation with physicians for joint clinical trials • Possibility to inform about own products • Possibility of being recognised as potential partner in R&I projects, supplier of medical devices and dialogue partner • Support of marketing activities

Table 4: Industry's needs

3.6. Local governments

3.6.1. Description

Local governments are the administration of one of the smallest administrative division inside a country. However, the scope (responsibilities, power) and territory of local governments in the BSR varies significantly between countries. They often have only limited funds at hand and operate on a small budget, focusing exclusively on local matters and projects. The personnel consists of administrators and local politicians, who do usually not possess great technical expertise on medical topics. While domestic and trans-border cooperation with other local governments exists in the form of formal or informal partnerships and networks, the focus in their every-day work is very locally rooted. Local governments are often directly accountable to the local population and are held responsible for many decisions that directly influence the citizen's everyday life in their immediate environment.

The stakeholder group's main interests include:

- Promoting their region as an attractive location for business, investment, living, working and tourism
- An educated population to strengthen the labour market
- Providing a good and safe living environment for the population
- Good infrastructure on medical services

3.6.2. Needs

- Being informed about hospitals in their region participating in the BFCC or taking part in R&I collaboration (projects) for supporting location marketing initiatives
- Concise, easy to understand information about BFCC and how the region/municipality profits from it (not too technical, rather abstract) → possibility to pass on the news, e.g. to local newspapers and the citizens directly

3.7. National governments/EU

3.7.1. Description

National and EU authorities' staff consists of policy makers, politicians and administration personnel. Looking at the represented professions, it is a heterogeneous group that is sharing the position in the field of tension between politics and economics. They are working for the identified common good or common interest of the population on the one hand, while also pursuing their own political or administrative agenda. The work environment inside and between these authorities is often highly bureaucratic, and characterised by strict hierarchies and the importance of established and standardised processes. The authorities operate in the frame of national and EU policies which constitute long-term strategies. As a result, these institutions are usually relatively inflexible when it comes to spontaneously react to external influences, and unable to quickly make decisions, even necessary ones, when a certain degree of urgency is given. This must be kept in mind at all stages of collaboration with this stakeholder group. While health care is usually considered to be of utmost importance on the policy level, many administrators and even decision makers do not possess technical expertise on medical topics and need to be approached with clear proposals.

The stakeholder group's main interests include:

- Getting the highest possible output out of valuable tax money
- Providing funds for quality projects fulfilling the strategic objectives and common interest
- Lower costs and better quality healthcare suited for the needs of the population and sustainable, also adaptable to future needs
- Prevention of bone injuries / diseases
- Identifying and spreading best practices within the region, e.g. BSR, possibility to expand / spill over to other areas within the region and beyond
- Regulating the market for health products and services to ensure security and quality while still maintaining fair competition
- Boosting innovation
- Recognition as research and innovation country/region within Europe and beyond
- Promoting their country or EU as an attractive location for business, investment, living, working and tourism
- An educated population to strengthen the labour market
- Providing a good and safe living environment for the population
- Good infrastructure on medical services

3.7.2. Needs

- Acting in line with legal and regulatory framework conditions
- Attracting and supporting different players proactively contributing to the defined long-term strategies, e.g. via funding programmes
- Concise, easy to understand information which must be delivered straight to the right department / office / contact person or will most likely be disregarded

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4. HOSPITAL SPECIFIC FRAMEWORK CONDITIONS

4.1. Introduction

The cooperation between industry and hospitals is subject to different framework conditions covering regulatory, legal, organisational and financial issues depending on the country. From the following three hospitals are information available under which framework conditions the cooperation with industry takes place:

- University Medical Center Schleswig-Holstein, Germany
- University Hospital in Krakow, Poland
- University of Tartu, Estonia

4.2. Collaboration between industry and University Medical Center Schleswig-Holstein, Germany

Process of collaboration between industry and hospital using the example of a clinical study at the UKSH at the Institute of Orthopedics and Trauma Surgery.

There are FOUR ETHICAL PRINCIPLES according to which clinical studies are conducted:

PRIMUM NON NOCERE

Not harm at first, consider whether the results of the study will benefit society without harming the subjects participating in the study

RESPECT

Participants' consent after clarification, which must be comprehensive and understandable. Participation is voluntary and all patient data will be treated confidentially

PROVIDENCE

Thorough risk-benefit assessment

JUSTICE

Applies to all procedures used to select subjects to participate in studies

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UKSH
Many principles for conducting clinical trials are already defined in the Recommendations on Good Clinical Practice (ICH — GCP) and in the Helsinki Declaration In Germany, there are legally binding regulations for clinical studies with medical devices, which are laid down in the Medical Devices Regulation. The European standard is defined in ISO standard 141556	NEEDS ASSESSMENT, IDEA DEVELOPMENT, test plan (study protocol: Duration of the study, criteria for selection of subjects, definition of tests / procedures, which drug in which dosage, definition of medical care beyond the end of the study…)	
The company itself must research and find out which hospital is suitable for participation in the clinical study (sufficient number of patients, study physicians…) and who the contact person in the hospital is	ENQUIRY TO HOSPITAL	
		Enquiry goes directly to contact person in the hospital, usually senior physician of a section / area or head physician
Considerations about the study, number of patients, how fast is inclusion possible, number of employees, duration (how many visits, how long does a visit take…), premises, procedures, execution, type of documentation, time required for documentation → internal effort and costs		TENDER OFFER
		OFFER to enterprise
	Evaluation, comparison of the offer	

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UKSH
	Sending a STANDARD CONTRACT to hospital	
Review of the contract, advice on legal issues, drafting of contracts, drafting of opinions, legal opinions		Forwarding of the standard contract to the legal office for review
UKSH regulation: calculation sheet with information on expected income, personnel costs, material costs, etc.		Fill in a calculation sheet
Review of the calculation values and plausibility and clarification of legal issues in third-party funding contracts in cooperation with the legal department		Forwarding of the standard contract and the calculation sheet to the third-party funds department UKSH for review
	Adjustments to the draft contract	
	CONTRACT SIGNED BY COMPANY REPRESENTATIVES	CONTRACT SIGNED BY CLINIC DIRECTOR, PROJECT MANAGER, INVESTIGATOR
UKSH regulation: For studies conducted in cooperation with several clinics or institutes of the faculty, the signatures of all directors are required		Statement Clinic Director
UKSH regulation: Fill out the standard document with investigator information on potential economic and other interests in the conduct of clinical trials		Principal investigator
	START of the clinical study	
	Handover of medical devices, forms, information material etc. to the participating hospitals	

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UKSH
		Determination of physician and study assistant, creation of the folder structure for the project with contract file and other documents
		Information about the start of the study at UKSH about posters, mails with reference to inclusion criteria and further information (flyer etc.)
Once a funding key has been allocated, all activities related to the research project are recorded in the accounts, e.g. staff recruitment, travel expenses and the purchase of equipment		THIRD-PARTY FUNDS DEPARTMENT
The members of the faculty are obliged to test new diagnostic and therapeutic procedures, including the examination of medicinal products and medical devices that have not been approved or approved but not yet sufficiently tested, as well as new methods of scientific research on humans only if a positive opinion of the Ethics Committee is available		ETHICS COMMITTEE • University Lübeck • Kiel University • Ethics Committee at the Schleswig-Holstein Medical Association
		EXECUTION of the clinical study
A particularly important aspect of the Helsinki Declaration is the informed consent of the participant after clarification		Patient inclusion, information and declaration of participation Carrying out the visits Logging of visits in the Case Report Forms (CRFs) Invoicing etc.

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UKSH
A clinical monitor checks that the requirements of Good Clinical Practice, the Declaration of Helsinki and the corresponding laws and regulations (e.g. Medicines Act, Medical Device Regulation) of the individual countries are observed The monitor presents the requirements of the study to the investigators involved in the study, provides them with study materials and also monitors exact compliance with all requirements		MONITORING is performed by an external clinical monitor
		COMPLETION of the clinical study
		Handover of the collected data, the completed documents, the remaining medical devices, project completion report, etc. to the company
		Final invoice, closing of the third-party funded project by the third-party funding department, information to project manager
	EVALUATION OF THE RESULTS OF THE CLINICAL STUDY	
	CONSIDERATIONS for carrying out another clinical study with a different focus of investigation (collection of ideas) and EVALUATION of the cooperation with the hospitals	LESSON LEARNED with all persons involved in the study

Table 5: Collaboration between industry and University Medical Center Schleswig-Holstein, Germany

4.3. Collaboration between industry and University Hospital in Krakow, Poland

Process of collaboration between industry and hospital using the example of a clinical study.

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
The legal basis for clinical trials may include: • Pharmaceutical Law Act • Act on medical devices • Act on the profession of doctor and dentist • Implementing regulations to the above-mentioned laws • GCP etc.		The legal basis for clinical trials may include: • Pharmaceutical Law Act • Act on medical devices • Act on the profession of doctor and dentist • Implementing regulations to the above-mentioned laws • GCP etc.
The company itself must research and find out which hospital is suitable for participation in the clinical study (sufficient number of patients, study physicians...) and who the contact person in the hospital is		Initiation of the process leading to the start of negotiations on the contract for a clinical trial is carried out by contacting the Sponsor / Principal with the Main Investigator or the Center for Innovative Therapy (CIT) UHK
	Sponsor / Client after contacting the Main Researcher and obtaining his consent, he asks to conduct research at the University Hospital by sending the application to the following address: badaniakliniczne@su.krakow.pl	
Considerations about the study, number of patients, how fast is inclusion possible, number of employees, duration (how many visits, how long does a visit take...), premises, procedures, execution, type of documentation, time required for documentation → internal effort and costs		The Chief Researcher receives from the Sponsor the Clinical Trial Protocol, a summary of the methodology of a clinical trial in Polish, a model for a clinical trial with attachments to the contract (copy of the insurance or promise, copy from the National Court Register or its equivalent, necessary power of attorney) and the proposed budget research

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
	In order to sign the contract, the Main Investigator or Technical Coordinator of the audit submits the following documents to the CIT: 1 Application for the conclusion of a clinical trial contract, in accordance with the model, Annex No. 3 SOP-BK-06a, also an e-document 2 The protocol of the clinical trial 3 Three-party agreement — a project, also an e-document 4 Sponsor and Investigator Civil Insurance Policy or promise of a policy 5 Current copy from the National Court Register or its equivalent, referring to the Sponsor/Client 6 Summary of the clinical trial methodology in Polish along with the test scheme from the test report 7 Patient treatment plan in accordance with the model, Appendix No. 1 SOP-BK-06a, also an e-document 8 The budget proposal in accordance with the formula, Annex No. 2 or Annex No. 2.1 to SOP-BK-06a, also an e-document 9 Information on establishing cooperation rules within the framework of the study between organizational units/ organizational units of the Hospital, and GB/GB syndrome, if applicable	

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
		The Clinical Trial Team starts negotiations on the contract for a clinical trial after receiving the complete set of documents listed above (Preparation and submission of the application) The lack of a complete set of documents makes it impossible to start negotiations, except to start a legal analysis of the contract for a clinical trial
		The hospital reserves the right to carry out the analyses referred to in the point above and to prepare the contract with attachments up to 20 working days from the date of receipt of the set of documents In the case of formulating queries and comments to the contract, patient treatment plan or budget proposal from the Clinical Research Team, the time to determine the final shape is extended accordingly by the number of days waiting for the written response of the Main Investigator / Sponsor
Review of the contract, advice on legal issues, drafting of contracts, drafting of opinions, legal opinions		The contract for conducting a clinical trial includes provisions regarding the hospital's payment of the initial payment (charged after the conclusion of the contract) and an annex fee (charged in the case of signing an annex including a change in financial terms), paid by the Sponsor / Ordering party The fee may not be lower than PLN 3000 and PLN 1000, respectively
UHK regulation: calculation sheet with information on expected income, personnel costs, material costs, etc.		Fill in a calculation sheet

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
Review of the calculation values and plausibility and clarification of legal issues in third-party funding contracts in cooperation with the legal department		The Sponsor submits the printed, necessary number of copies of the final contract to the Legal Department (DP) of the Hospital, in order to submit them (after being initialized by DP and Legal Adviser) for signature to the Chief Accountant, Hospital Director and Chief Investigator Signed copies of the contract, DP sends to the Sponsor a survey to sign the contract. Sponsor/Customer returns signed copies to DP DP gives the Main Investigator a copy of the signed contract
	RENEGOTIONS AND APPROVAL OF THE AGREEMENT 1 An application for a change of the contract submitted by the Sponsor/Principal or Main Investigator is subject to the analysis of the members of the Clinical Trial Team, subject to the deadline for analysis not longer than 14 days 2 In the case of signing an annex covering a change of financial conditions, an annex fee is charged as described above	
	CONTRACT SIGNED BY COMPANY REPRESENTATIVES	CONTRACT SIGNED BY CLINIC DIRECTOR, PROJECT MANAGER, INVESTIGATOR
UHK regulation: For studies conducted in cooperation with several clinics or institutes of the faculty, the signatures of all directors are required		Signature of the Chief Accountant, Hospital Director and Chief Investigator

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
UHK regulation: Fill out the standard document with investigator information on potential economic and other interests in the conduct of clinical trials		Signature of the Chief Accountant, Hospital Director and Chief Investigator
	START of the clinical study	
	Handover of medical devices, forms, information material etc. to the participating hospitals	
		Determination of physician and study assistant, creation of the folder structure for the project with contract file and other documents
		Information about the start of the study at UHK
Once a funding key has been allocated, all activities related to the research project are recorded in the accounts, e.g. staff recruitment, travel expenses and the purchase of equipment		UHK keeps records of all costs related to the study
The members of the faculty are obliged to test new diagnostic and therapeutic procedures, including the examination of medicinal products and medical devices that have not been approved or are approved but not yet sufficiently tested, as well as new methods of scientific research on humans only if a positive opinion of the Ethics Committee is available		• Bioethical Committee of the Jagiellonian University • Bioethics commissions of the Regional Medical Chamber
		EXECUTION of the clinical study

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UNIVERSITY HOSPITAL IN KRAKOW
A particularly important aspect of the Helsinki Declaration is the informed consent of the participant after clarification		Patient inclusion, information and declaration of participation Carrying out the visits Logging of visits in the Case Report Forms (CRFs) Invoicing etc.
A clinical monitor checks that the requirements of Good Clinical Practice, the Declaration of Helsinki and the corresponding laws and regulations (e.g. Medicines Act, Medical Device Regulation) of the individual countries are observed The monitor presents the requirements of the study to the investigators involved in the study, provides them with study materials and also monitors exact compliance with all requirements		MONITORING is performed by the Center for Innovative Therapy (CIT) UHK
		COMPLETION of the clinical study
		Handover of the collected data, the completed documents, the remaining medical devices, project completion report, etc. to the company
		Final invoice, closing of the project, information to project manager
	EVALUATION OF THE RESULTS OF THE CLINICAL STUDY	
	CONSIDERATIONS for carrying out another clinical study with a different focus of investigation (collection of ideas) and EVALUATION of the cooperation with the hospitals	LESSON LEARNED with all persons involved in the study

Table 6: Collaboration between industry and University Hospital Krakow, Poland

4.4. Collaboration between industry and University of Tartu, Estonia

Process of collaboration between industry and hospital using the example of a clinical study at the University of Tartu.

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UNIVERSITY OF TARTU
Clinical trials are conducted by following standards: Good Clinical Practice (GCP), Helsinki Declaration The European standard is defined in ISO standard 141556	Needs assessment, idea development, test plan (study protocol: Duration of the study, criteria for selection of subjects, definition of tests/procedures, which drug in which dosage, definition of medical care beyond the end of the study...)	
The company itself must research and find out which hospital is suitable for participation in the clinical study (sufficient number of patients, study physicians...) and who the contact person in the hospital is	Identifies suitable hospital for the research Enquiry to hospital	Our laboratory is in the hospital and offers following measurements in addition to regularly used medical diagnostics: • anthropometric • goniometry • electromyography • handheld muscle dynamometry • functional tests • hand grip dynamometry • dynamographic and -metric assessment • densitometry • pain assessment (visual analogue scale and pain pressure threshold) • different questionnaires for function and quality of life REDCap licence for creating online databases
		Enquiry goes directly to contact person in the hospital, usually head of clinic, senior physician of a section/area or head physician or Clinical Research Centre

FRAMEWORK CONDITIONS/ REMARKS	INDUSTRY/ENTERPRISES	UNIVERSITY OF TARTU
Considerations about the study, number of patients, how fast is inclusion possible, number of employees, duration (how many visits, how long does a visit take...), premises, procedures, execution, type of documentation, time required for documentation → internal effort and costs	Come to an agreement on research design, budget and action plan	
		Contact person sends initial draft of the research project to hospital's research counsellor
		Study is registered in hospital's research database
Ethics committee application also works as a study protocol for hospital's research database Contact person sends application to Research Ethics Committee of the University of Tartu for approval		Contact person applies for ethics approval
In general, overhead is 20% of whole budget of the project Overhead is not requested for the supplies provided by the enterprise	Contract between the hospital and the enterprise (hospital agreement)	
	Contract between the institute of the university/clinic and the enterprise (researcher agreement)	
	START OF THE CLINICAL STUDY	
	Handover of medical devices, forms, information material etc. to the participating hospitals	

FRAMEWORK CONDITIONS / REMARKS	INDUSTRY / ENTERPRISES	UNIVERSITY OF TARTU
Every patient needs to sign informed consent and patient information form		Patient recruitment, information and declaration of participation Carrying out the visits Logging of visits in the Case Report Forms (CRFs) Invoicing etc.
Previous clinical trials have passed regular audits by FDA and EMEA		Clinical Research Centre performs monitoring of the study
	COMPLETION OF THE CLINICAL STUDY	
		Handover of the collected data, the completed documents, the remaining medical devices, project completion report, etc. to the company
		Final invoice, closing of the third-party funded project by the third-party funding department, information to project manager
	Evaluation of the results of the clinical study according to the contract details	
	CONSIDERATIONS for carrying out another clinical study with a different focus of investigation (collection of ideas) and EVALUATION of the cooperation with the hospitals	LESSON LEARNED with all persons involved in the study

Table 7: Collaboration between industry and University of Tartu, Estonia

5. BFCC PILOT EXPERIENCES IN COLLABORATION OF INDUSTRY AND HOSPITALS

5.1. Introduction

The experiences made in the BFCC project regarding the collaboration of industry with hospitals are explained in detail in a separate report, the Evaluation Report. In the following, some excerpts were used to show which challenges companies and hospitals have to face in order to successfully and jointly achieve the set project goals.

An online survey was created and made available to all participants of the three pilots to get information about the collaboration of industry and hospitals. The online survey was divided into four complementary fields such as:

- Group communication within the pilot
- Pilot performance and usability
- User satisfaction
- Challenges and weaknesses of operational framework

5.2. Group communication within the pilot

5.2.1. Introduction

In the area of group communication within the pilot, questions were asked about the general assessment of the group communication as well as questions about any kind of problems that may have occurred in the communication between the various partners.

5.2.2. General assessment of the group communication

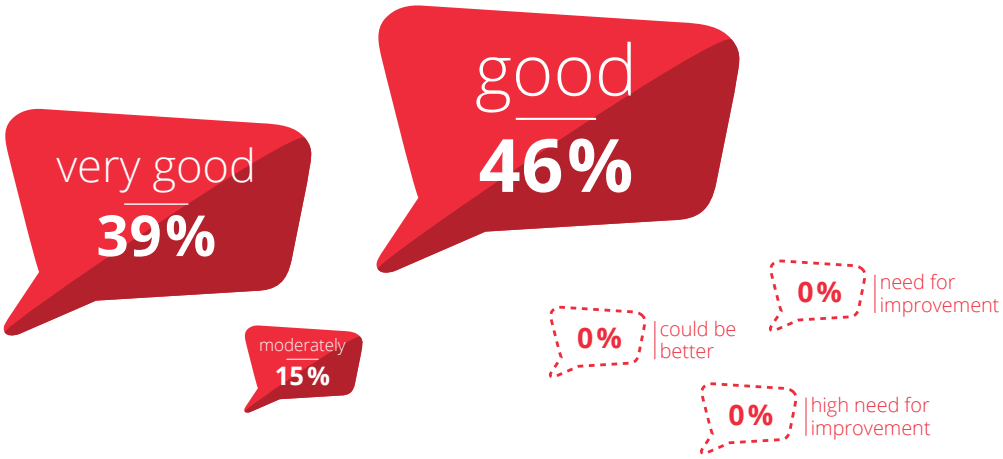


Figure 2: Online Survey—Assessment of communication in general

The group communication in general was rated as very good or good by 85% of the participants, overall it was called an open and good communication. Some of the participants mentioned, that the attendance discipline to calls and efficacy of calls could be improved and more face-to-face meetings in smaller working groups had to be scheduled.

5.2.3. Communication problems

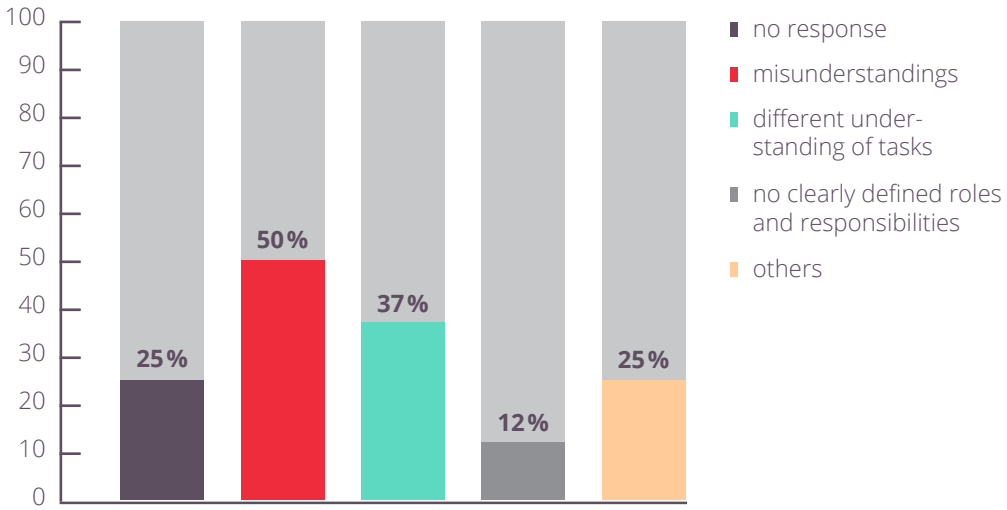
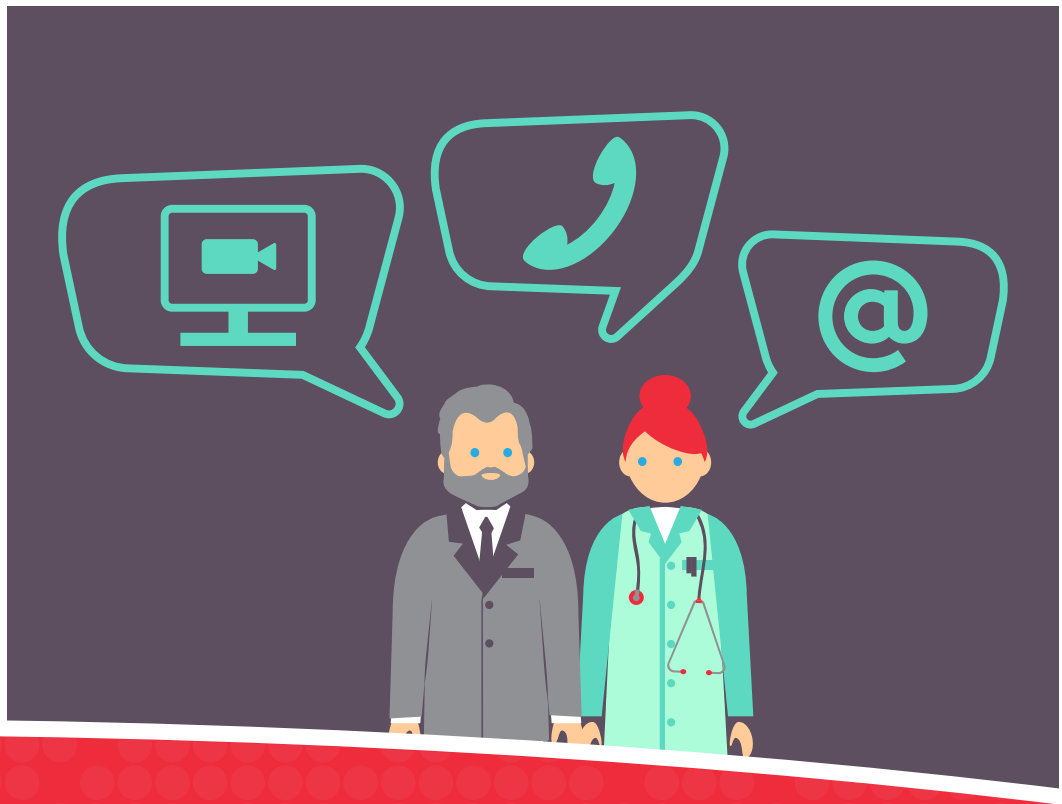


Figure 3: Online Survey — Communication problems (multiple answers possible)

Misunderstandings, named by 50% of the participants, and the different understanding of tasks, named by 37% of the respondents, at the start of the project were the biggest problems in the area of communication with which the partners had to struggle. These problems would not have occurred at personal meetings or could have been solved more easily, but of course the budget must also be taken into account as well as daily workload. Costs on travel and accommodation to meet personally would have to be increased in the budget. Some of the communication problems occur more frequently at the beginning of a project, while others occur repeatedly throughout the entire project duration.

Some comments from the participants for section »others« are listed below:

- Lack of attendance
- Some actions (as changes in plan and submission of abstract) had already occurred when we were informed



5.3. Pilot performance and usability

5.3.1. Introduction

In the area of performance and usability the participants were asked for methodical challenges they have faced during the study.

5.3.2. Methodical problems and challenges

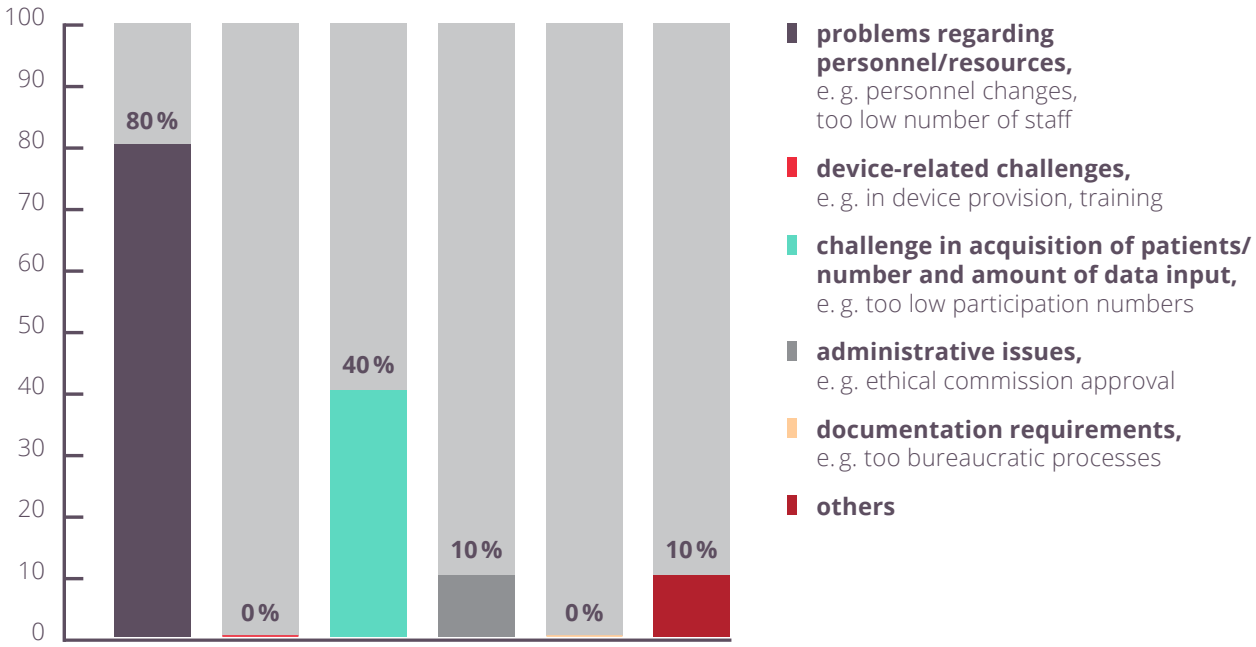


Figure 4: Online Survey—Methodical problems and challenges (multiple answers possible)

An overwhelming majority of participants (80%) named personnel and other resources, e. g. personnel changes, too low number of staff followed by challenge in acquisition of patients, number and amount of data input, e. g. too low participation numbers (40%) as the main problems in the implementation of the project. One partner mentioned in the survey that there were delays in the study due to staff restrictions at the participating hospital.

5.4. User satisfaction

5.4.1. Introduction

What was the specific benefit / added-value for your organisation? What has to be improved in future research and innovation (R&I) collaboration? Would you recommend transnational collaboration between industry and hospitals? These three important questions should be answered by the participants in the user satisfaction area.

5.4.2. Specific benefit / added-value for the organisation

The comments from the participants of the survey are listed below:

- Learn about hospital IT data systems
- Valuable exchange with project partners
- More data about how our products work, i. e. elutes antibiotics, but also a deeper knowledge in this important and critical area (infections connected to fractures)
- We started using Bindex®

5.4.3. What has to be improved in future research and innovation collaboration?

Some of the participants' suggestions for an improved research and innovation collaboration are listed below:

- More direct face-to-face interaction
- Define clear goals at start of project
- Strong commitment from all stakeholders
- Communication is always the key and efforts to improve it should be supported

5.4.4. Recommendation of collaboration between industry and hospitals

Currently, 12 out of 14 participants in the survey support transnational cooperation and would recommend it to others, 2 participants skipped the question.

5.5. Challenges and weaknesses of framework conditions

5.5.1. Introduction

In this area, the participants were asked for system weaknesses or challenges of operational framework conditions and what the main strength of hospital and industry collaboration means for them.

5.5.2. System weaknesses of operational framework conditions

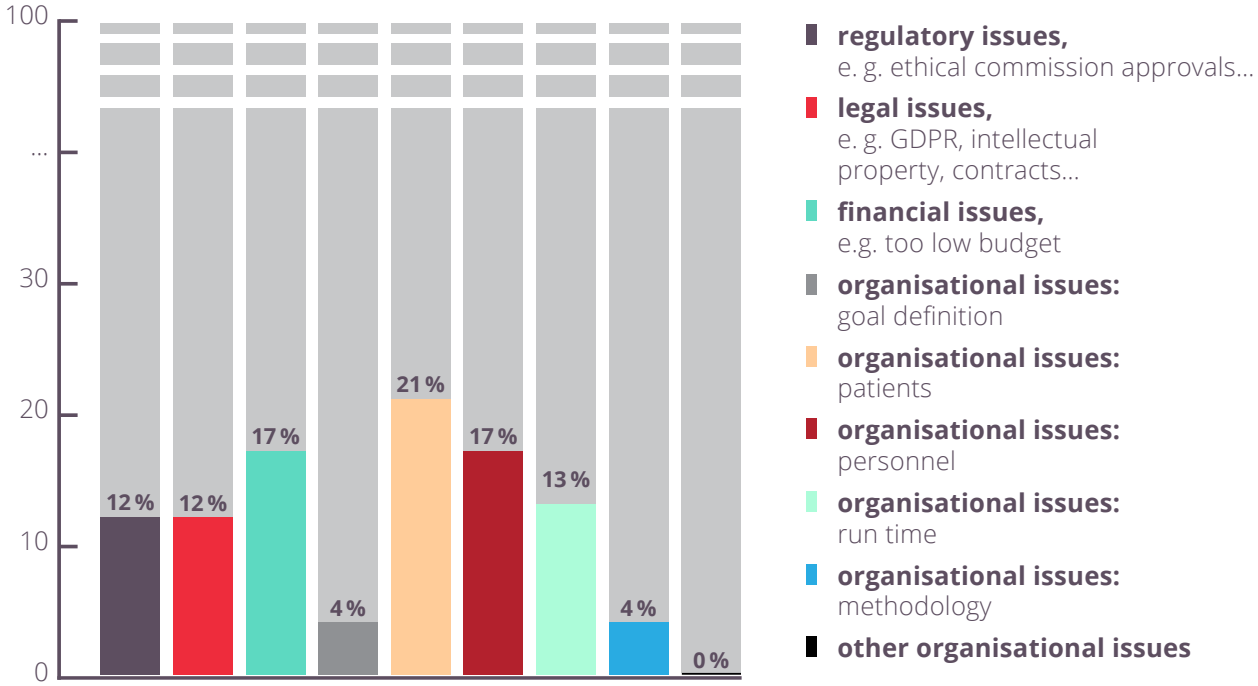


Figure 5: Online Survey — Challenges of operational framework conditions (multiple answers possible)

In the survey, the participants named the organisational issues such as patients (21%), staff (17%) and financial issues, such as too low a budget (17%) as the system challenges of operational framework conditions, which they had found the most demanding.

Here are some comments made from different partners:

- It gets more and more difficult to establish collaboration between industry and healthcare providers due to legal and compliance reasons. Registry needs sustainable concept to ensure continuity after project ends.

- My response above is for future »collaboration hospital–industry« and not for the pilot project one we just have had. The new Medical Device Regulation will require a lot from Medical Device companies in the future — on all levels.

5.5.3. Main strength of hospital and industry collaboration

Here are some comments made from different partners:

- The ability to quickly respond to needs.

- Healthcare needs innovation and so hospitals and industry need to collaborate closely. Industry needs to understand the clinical needs and hospitals need to understand the industrial framework (compliance, legal, IP, regulatory) to set common goals that are achievable, profitable and solve the healthcare need.

- As an innovative medical device company you want to have as much clinical data and »in-put/feedback from users« as possible. To get this information, you need to have close and controlled collaboration with hospitals who are using your products in a controlled way (be in compliance with MDR). This »BFCC-collaboration project« has improved our knowledge about one of our products. We are very satisfied with the opportunity to a hospital–industry collaboration the BFCC Project gave us.

- Our capacity as innovation infrastructure has improved.

5.6. Conclusion

The majority of the questioned partners are in favour of transnational cooperation and would recommend it to others. However, this did not function quite smoothly and there are one or two points that should be improved in the future.

The communication in the pilots can be described as open and constructive. In order to avoid misunderstandings and different understandings of tasks in the future, there should be more meetings at the beginning of projects, in which the participants meet personally and, thus, be able to develop a common understanding for the upcoming tasks. It is important that the partners within their organisations give a clear commitment to the projects and that you can rely on the input of the work package partners during the course of the project. It should not be the case that the work agreed upon is not delivered or not delivered on time.

Many partners face restrictions in human resources (too few employees or frequent changes) and the limited financial budget, as well as sufficient patients who meet the inclusion criteria to be included in the study — due to a lack of personnel on the one hand and patients who do not meet the criteria on the other. In the survey, the participants named the organisational issues such as patients, staff and financial issues, such as too low a budget, as the most important system challenges of operational framework conditions. Thus, there is great correlation between the methodological problems and challenges and the weaknesses in the system.

Based on the experience gained by the partners in the pilots in the cooperation between industry and hospitals and the online survey that was conducted, it is possible to draw conclusions for improved framework conditions that have an impact on the BFCC collaboration platform.

6. PRINCIPLES OF INDUSTRY—HOSPITAL COLLABORATION ADOPTED BY THE BFCC CONSORTIUM

The four principles of Industry–Hospital Collaboration adopted by the BFCC consortium:

- Principle of separation
- Transparency/approval principle
- Equivalence principle
- Documentation principle

6.1. Principle of separation

The separation principle states that benefits to clinicians and other employees of medical institutions as well as to practicing physicians may not be abused in order to influence them in their therapy, prescription and procurement decisions in an unfair manner. The idea is already to avoid the impression that donations influence procurement decisions. Furthermore, no benefits may be granted for the private purposes of the respective recipient.

In general, payments for studies as well as post-marketing surveillances must always be directly transferred to the medical facility or to a third-party account.

Invoiced sales must be strictly separated from all other forms of cooperation. Other collaboration with hospitals and physicians may never be connected to purchasing decisions.

6.2. Transparency/approval principle

The transparency/approval principle states that benefits that can gained by clinicians or other employees of medical facilities must be disclosed to the respective employer (transparency principle) and must be approved by them (licensing principle). The actual and legal pre-examination of a transaction by the employer usually precludes or at least largely eliminates the possibility of the granting of an influence on official decisions of the physician, in particular on procurement decisions. Strict compliance with the principle of transparency/approval also complies with the requirements of employment law and at the same time prevents criminal liability for the granting of benefits or the acceptance of benefits.

6.3. Equivalence principle

According to the principle of equivalence, performance and consideration must be in reasonable proportion to each other in contractual relationships. The calculation of the remuneration for services rendered by physicians and medical facilities to medical device companies shall be determined in particular by the scope of the service, the time required and the particular qualification of the contracting party. The remuneration must be within the scope of what is customary in the case of corresponding contractual relationships.

Whether performance and consideration are in reasonable proportion to each other, among other things, judges whether the remuneration is in a reasonable, so factually justified relationship to the time and the difficulty of the task. Other criteria, such as the individual competence of the medical contractor, are also important in determining the appropriateness of performance and consideration.

6.4. Documentation principle

According to the documentation principle, compliance with the above principles should be documented in all forms of cooperation with doctors and medical institutions. Agreements with doctors and medical institutions must therefore be made in writing. Proper provision of the contractually agreed services must also be proven by means of suitable documents (e. g. invoices, statements of services rendered, written reports, manuscripts, etc.). If necessary, evidence of the appropriateness of the agreed remuneration (e. g. special qualification of the contract partner) must also be documented.

7. STANDARD PROCEDURE FOR COLLABORATION

7.1. Cooperation in the healthcare market

Behaviour recommendations for cooperating in the health-care market have existed for over ten years. These principles clearly stipulate which forms of cooperation are allowed for everyone involved, and describe unmistakable limits. The regulations, also embedded in the Medical Device Codex, make it possible for the Medtech manufacturers, pharmaceutical companies, hospitals and physicians to interact with each other on safe ground. Medical device companies are involved daily in a variety of work relationships and contacts with employees of medical institutions. This does not only apply to the distribution and promotion of products as well as the advice of physicians when using medical devices.

Rather, the manufacturers of medical devices also rely on close cooperation with the clinics and doctors, especially in the areas of research and development as well as clinical trials. After all, proper therapy decisions and the correct use of medical devices depend decisively on physicians adhering to the current state of research and knowledge.

While legal regulations in the area of medical device sales prescribe a strict separation between industry and physicians in order to keep procurement and treatment decisions as uninfluenced as possible, the necessary cooperation between the medical device industries on the one hand and physicians and clinics on the other hand requires a special close relationship. The tension between »strict separation« and »close cooperation« creates a variety of legal problems that need to be dealt with in practice. Solving these problems is not always easy.

The Federal Association of Medical Technology e. V. (BVMed) in Germany has — in close collaboration with other leading associations in the health care sector — therefore assembled and published the Code »Medical Devices« as well as its participation in the »Common Position on Criminal Assessment of Cooperation between Industry, Medical Institutions and their Employees« contributed to the clarity that has now been achieved as to the conditions under which cooperation can take place. It takes care of all EU-wide regulations in this area and has been based on four principles. This guideline has been adopted for the BFCC to facilitate close collaboration whilst taking strict care of all compliance regulations.

7.2. Innovation cycle

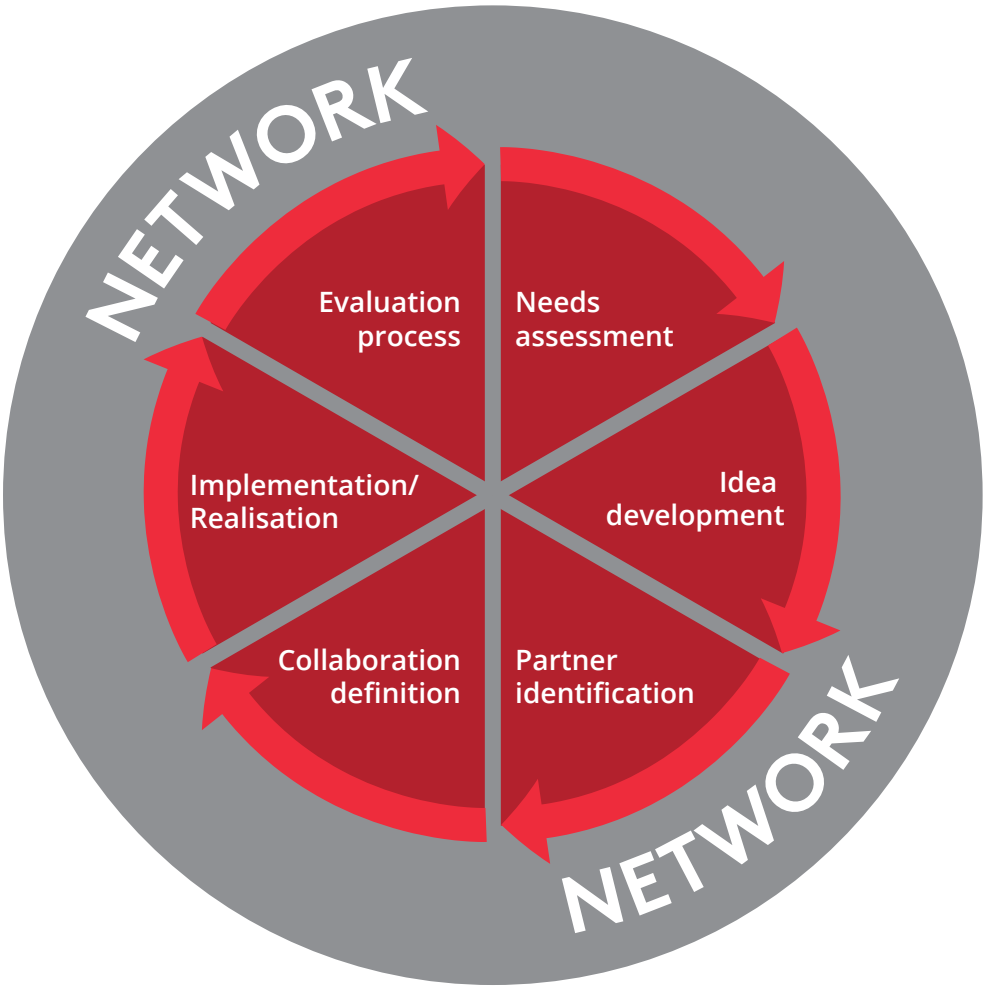


Figure 6: Innovation cycle

The BFCC Innovation cycle describes a standard procedure for collaborations between hospitals and industry. The collaboration platform covers the whole innovation cycle from needs assessment and idea development until the evaluation of outcome and collaboration.

The comprehensive network, consisting of various stakeholder groups interested in fracture treatment, supports and facilitates the cooperation between industry and hospitals, in which partners for projects can find each other more easily. With the data collected, the reports generated from them, the reports to be produced in the future and the conclusions for the correct treatment method, the registry offers an important and significant instrument for the involvement of further partners, interested parties and for cooperation between industry and hospitals.

#	PHASE	QUESTION	METHODS	RESULT	PARTICIPANTS
1	NEEDS ASSESSMENT	Which discrepancy between the current condition and wanted condition exists?	• SWOT analysis • Force field analysis	List with needs and stakeholders	• Patients • Hospitals • Industry
2	IDEA DEVELOPMENT	Which ideas fit the identified needs the best?	• Stakeholder Meetings • Innovation Dialogue Events	List with ideas for projects, clinical trials, cooperation, products...	• Stakeholders
3	PARTNER IDENTIFICATION	Which partners/ institutions could help the best?	• Network platforms • Experiences	Identification of the most potential partner(s)	• Institutes • Hospitals • Industry
4	COLLABORATION DEFINITION	Which kind of collaboration is the best?	• Meeting/ Clarification	Contract Funding	• Partners
5	IMPLEMENTATION	What is the best way for implementation?	• Lean Project Management • Network planning technology	Product/ Method (new or improved) Database (Registry) Reporting/ Documentation	• Partners
6	EVALUATION OF OUTCOME AND COLLABORATION	What have the partners learned during the process?	• Lesson learned	Overview of improvements in terms of project structure, planning, implementation, steering List with new project ideas	• Partners

Table 8: Phases of the innovation cycle

The table above shows the individual phases of the innovation cycle. The phases were supplemented with additional information such as questions to be answered in the phases, methods used, expected results and partners involved. This makes it clear how complicated each of these phases is, for example in a clinical study or other research projects. In the entire innovation cycle, the partners must work together as smoothly as possible, i. e. communication in a project makes a decisive contribution to the success or failure of a project.

Medical facilities and their employees may only be selected to conduct research and development projects if they can demonstrate they possess the respective professional qualifications and technical equipment for the subject. Furthermore the enterprise must have a comprehensible interest in the collaboration, and the scientific value must be proven and documented.

7.3. Procedure for interested stakeholders

As mentioned in former chapters, the collaboration platform is defined as competence centre combining the three elements data transfer (registry), knowledge transfer (e. g. website, education) and network and collaboration.

Table 9 below explains the icons used in different tables in sub-chapter 7.3. Procedure for interested stakeholders.

		
IMPLEMENTED	IN PROGRESS	NOT IMPLEMENTED

Table 9: Legend of tables 10–12 (coverage collaboration platform — stakeholder needs)

7.3.1. Data transfer — registry

An interested stakeholder can acquire information from the BFCC website, like:

- How to become a partner of BFCC transnational registry
- Video »How to get access to the BFCC — easily explained« explains step by step how hospitals can register with the TFRP to participate and enter patient data
- How to get data and reports from the fracture registry

The following overview compares the coverage of the current collaboration platform — element data transfer (registry) — with the needs of the individual target groups analysed in the chapter Stakeholders.

PHYSICIANS' NEEDS AS REGISTRY USERS	CHECK
A reliable and interactive »Encyclopaedia« of bone fractures and treatment data with a helpful search function and image material (if applicable)	✓
A large amount of data is needed to provide for the full functionality of the tool. But: The larger the individual dataset, the more mistakes will occur (which lead to decreased data quality) and the less likely physicians are to be persistent in filling out all fields for each patient	↗
Possibility to identify or contact the author of specific entries in case of further inquiries	✓
PHYSICIANS' NEEDS AS DATA SUPPLIERS	**CHECK**
A positive cost/benefit situation → The usefulness and functionality of the tool (see ›physicians as user of the registry‹) must outweigh the amount of time or resources spent to get familiar with the tool and the time needed to enter/maintain data in it	↗
Possibility for cross-linking between different registries used at their hospital and in their region to save time and get the full picture of a case	✗
Guidelines for using the registry (FAQ)	✓
Guidelines for data protection of patients	✓
RESEARCHERS' NEEDS	**CHECK**
A source for clinical information which can be easily accessed	✓
A great amount of available data of high data quality	↗
An automatic data analysis for quantitative, statistical evaluations (saving time for manual study), yet the possibility for gaining qualitative insights through the study of specific cases	✓
Need for detailed information, demonstrated utility and sophisticated analysis in order to be able to trust BFCC as scientific source	↗
Categorical search parameter (good search tool required) for individual data search	✓
Cross-linking possibilities between different registries to get the full picture	✗

HOSPITAL MANAGEMENT'S NEEDS	CHECK
The assurance that BFCC / registry is on the positive side of a cost / benefit analysis — it cannot take up too much time and resources in the busy schedules of a region's leading hospital, e.g. facilitation of data transfer through interface among BFCC and hospital information system	✗
In the best possible scenario, the BFCC would finance the human resources required to carry out data sampling and maintenance of the data in the tool	✗
Quality control ensuring the accuracy and reliability of the data gaining valuable input for the hospital's quality management system (for quality increase and cost efficiency)	↗
Instructions on the technical operation of the registry and how to disseminate the software to the relevant physicians, support in organisational, administrative and training issues → the least possible efforts at hospital side	↗
INDUSTRY'S NEEDS	**CHECK**
Being included with own products in the registry's dataset	✓
Facilitation of access to high quality real-life data for better cost-benefit ration of R&D processes and assessment of own products' efficacy	✗
Gaining specific insights in their products' use, complications, and needs for improvement	↗
Possibility to compare own products with others	✗
Possibility to quickly and accurately identify potential for innovation	↗
Facilitation of meeting regulatory framework conditions, e. g. Medical Device Regulation	↗

Table 10: Coverage collaboration platform — data transfer — stakeholder needs

Additional information regarding general requirements for cross-border use of patient registries including different aspects, for instance legal, semantic or technical aspects from the Guidelines of the Cross Border PAtient REgistries iNiTiative (PARENT), is part of the appendix.

7.3.2. Knowledge transfer

An interested stakeholder can acquire information from the BFCC website, like:

- Interesting facts about the project and the collaboration platform
- Information and recommendations about analysed innovation needs and clinical best practices
- In-depth information about fracture, such as Innovation Reports
- Detailed information about the three pilot demonstrations
- First findings from the BFCC project activities in the innovation library
- Video »How to get access to the BFCC — easily explained« which explains how to get access to BFCC registry, and, thus, how to collaborate with BFCC

The following overview compares the coverage of the collaboration platform — element knowledge transfer — with the needs of the individual target groups analysed in the chapter Stakeholders.

PHYSICIANS' NEEDS	CHECK
A handy opportunity for knowledge management and knowledge transfer for all types of bone injury / diseases, possible complications and treatment methods	✓
Well-structured and easily accessible information, e.g. on website	✓
Exchange of best practices and experiences with other physicians, hospital managers, researchers and industry from the BSR	✓
RESEARCHERS' NEEDS	**CHECK**
Facilitation of access to sources and target groups of research results	✓
Exchange of experiences and research results with hospitals, physicians and industry representatives	✓
HOSPITAL MANAGEMENT'S NEEDS	**CHECK**
Information about the BFCC and the registry	✓
Possibility for affordable further education / specialisation of staff	↗
Receiving performance reports including data of other institutions for comparison	✓
Exchanging best practices and experiences with other hospital managements (learning from each other)	✓

INDUSTRY'S NEEDS	CHECK
Access to innovation dialogue activities with hospitals, physicians and industry representatives	✓
Access to collected information on performance, safety and suitability of several industrial treatment processes for better collaboration and post market surveillance	✓
LOCAL GOVERNMENTS' NEEDS	**CHECK**
Concise, easy to understand information about BFCC and how the region / municipality profits from it (not too technical, rather abstract) → possibility to pass on the news, e.g. to local newspapers and the citizens directly	↗

Table 11: Coverage collaboration platform — knowledge transfer — stakeholder needs

7.3.3. Network and collaboration

A network consisting of various stakeholders has been successfully established in the course of the project. Contacts with industry were established during the MDR feasibility study and also during the Innovation Dialogue Meetings in order to find out what tasks the industry will have to fulfil in order to meet the new requirements and how the stakeholder network could help them.

An interested stakeholder can acquire information from the BFCC website, like:

- Video »How to get access to the BFCC — easily explained« which explains how to get access to BFCC registry, and, thus, how to collaborate with BFCC
- Information regarding education and training, analysed innovation needs and clinical best practices
- Contact information for stakeholders interested in cooperation
- Information about BFCC, how it works as an accelerator for cooperation between industry and hospitals

The following overview compares the coverage of the collaboration platform — element network and collaboration — with the needs of the individual target groups analysed in the chapter Stakeholders.

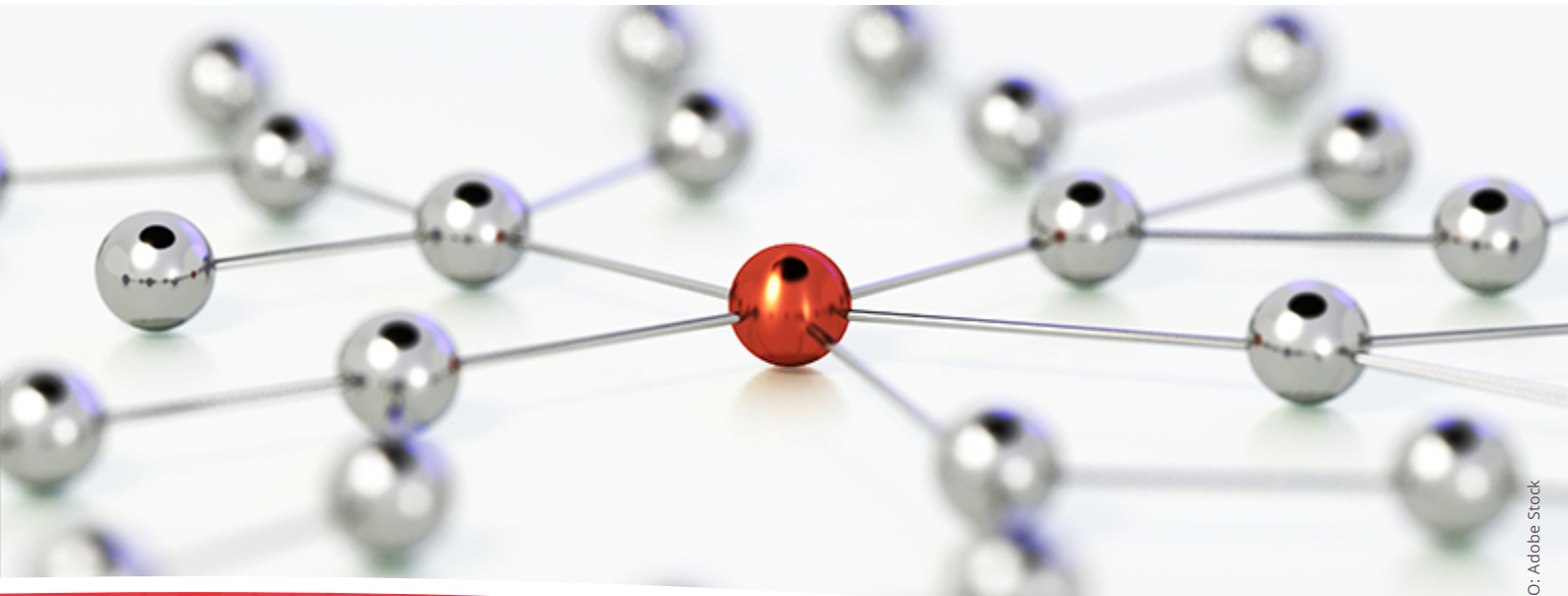


PHOTO: Adobe Stock

PHYSICIANS' NEEDS	CHECK
Facilitation of collaboration with industry and researchers with a clearly defined scope and designated roles and responsibilities	✓
Exchange of best practices and experiences with other physicians, hospital managers, researchers and industry from the BSR	✓
A similar level of expertise in the group (on a certain topic) to allow effective discussions	✓
RESEARCHERS' NEEDS	**CHECK**
A platform for collaboration with hospitals, physicians and industry with a clearly defined scope and designated roles and responsibilities	✓
Facilitation of access to new research fields, or rather fields of interest through scientific exchange	✓
Contact possibilities to potential funding sources, e.g. companies, for R&I projects	✓
Contacts possibilities to potential customers for research results, e.g. with regard to reports, patents	✓
HOSPITAL MANAGEMENT'S NEEDS	**CHECK**
A platform for collaboration with industry, researchers and authorities with a clearly defined scope and designated roles and responsibilities	✓
Possibility of spill-over effect and more (trans-border) cooperation with other hospitals also on other matters, which can lower costs and increase quality and effectiveness of care	✓
Possibility of spill-over effect and more (trans-border) cooperation with industry also on other matters	✓
Facilitation of contacts to possible employees	✗
Possibility for hospital presentation as site of interest for collaboration and as employer	✗

INDUSTRY'S NEEDS	CHECK
A platform for collaboration with hospitals and physicians with a clearly defined scope and designated roles and responsibilities	✓
Facilitation of cooperation with physicians for joint clinical trials	✓
Possibility to inform about own products	✗
Possibility of being recognised as potential partner in R&I projects, supplier of medical devices and dialogue partner	↗
Support of marketing activities	✗
LOCAL GOVERNMENTS' NEEDS	**CHECK**
Being informed about hospitals in their region participating in the BFCC	✓
Taking part in R&I collaboration (projects) for supporting location marketing initiatives	✗
NATIONAL GOVERNMENTS'/EU NEEDS	**CHECK**
Acting in line with legal and regulatory framework conditions	✓
Attracting and supporting different players proactively contributing to the defined long-term strategies, e.g. via funding programmes	↗
Concise, easy to understand information which must be delivered straight to the right department/office/contact person or will most likely be disregarded	✓

Table 12: Coverage collaboration platform—network and collaboration—stakeholder needs

8. OUTLOOK

There are some needs of stakeholders that the R&I collaboration platform does not yet meet. In a next step, it should be evaluated which of the still open requirements should perhaps be tackled in a follow-up project and of course, strategically implemented in the long-term BFCC organisation. If the remaining needs can also be covered with the collaboration platform, then this would strengthen the competence of the fracture registry as well as the companies in the BSR. The platform would then be of even greater benefit to companies, hospitals and other stakeholders in the BSR area.

It is conceivable that this project is going to be continued and that in this context the foundation of a company / institution is going to be dealt with, which is dedicated to the solution of the still pending, open tasks and their implementation. To improve health outcome further hospitals should be involve — the new founded institution should raise interest among stakeholders and establish partnerships. For the qualified exchange of knowledge, experience and challenges in the field of fracture management, there should be a continuation of the stakeholder meetings and the Innovation Dialogue Events. In this way, the already established network can be expanded with further qualified partners to provide answers to the most important (research) questions in fracture management.

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9. USED ABBREVIATION

ABBREVIATION/TERM	DESCRIPTION
BFCC	Baltic Fracture Competence Centre
BSR	Baltic Sea Region
BVMed	Federal Association of Medical Technology e.V. (Bundesverband Medizintechnologie e.V.)
GDPR	General Data Protection Regulation
EU	European Union
FAQ	Frequently asked questions
ICH — GCP	International Conference on Harmonisation — Good Clinical Practise
IT	Information Technology
MDR	Medical Device Regulation
R&D	Research and Development
R&I	Research and Innovation
SME	Small and Medium-Sized Enterprise
TFRP	Transnational Fracture Registry Platform
WP	Work Package

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11. LIST OF FIGURES

12. LIST OF TABLES

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13. APPENDIX

ADDITIONAL INFORMATION ON THE REGISTRY

General requirements for cross-border use of patient registries

The Cross Border PAtient REgistries iNiTiative (PARENT) guideline (PARENT, 2015), the result of a Joint Action under the EU's Health Programme, aims at providing recommendations and guidelines for the development of comparable (cross-border) registries. The BFCC develops and implements a Transnational Fracture Registry Platform (TFRP) of five hospitals from Germany, Lithuania, Poland, Estonia and Sweden, allowing a comparison of the process and outcome quality across the participating institutions and countries. The developed TFRP is built in accordance to the Guidelines of the Cross Border PAtient REgistries iNiTiative (PARENT). An excerpt from these guidelines can be found below.

Cross-border use of registries can take several different forms as the mapping work of PARENT has demonstrated, among others registry networks (e.g. the International Association of Cancer Registries, the Nordic Arthroplasty Register Association NARA), international clinical studies (GRACE — Global Registry of Acute Coronary Events) and international registries e.g. IBIR — International Breast Implant Registry). There are several strong drivers in using registry data across borders, such as the needs of studying differences between countries in morbidity, health system-level interventions' effectiveness and utility of procedures; the advantages of large international datasets vs. national ones in timely detection of rare, or previously unknown effects; gathering and promoting information on best practices worldwide.

Independent of the motive driving cross-border registries utilization, the success of the endeavour will always rely on the degree of achievement of certain prerequisites, the implementation of which starts at the local level — regional and/or national. PARENT Joint Action aims at the idea of establishing a continuous IT-assisted chain of health data capture, storage, processing, transmission and utilization. Therefore the purpose of fulfilling these prerequisites is the achievement of interoperability in the broadest understanding of the term, i.e. on legal, organizational, semantic and technical levels as well as the establishment of effective, sustainable solutions for cross-border registry collaboration.

Political context

The creation, maintenance and development of registries, as well as their preparedness for cross-border operations is largely dependent on the positioning (or lack thereof) of health data resources in national strategic prioritization regarding scientific data resources and research infrastructures. PARENT is analysing in a parallel activity national strategies and initiatives concerning Health Data and the ways in which they impact patient registry work.

Equally important is the question of whether registries are perceived as part of regional and/or national eHealth infrastructure. At the EU level, MS collaboration in the field of eHealth has until now focused primarily on the creation and exchange of health data at the point and for the purposes of patient care, as reflected in the work of the eHealth network on ePrescription and Patient Summary. The needs and requirements of secondary use of data, where the formation and utilization of registries also belongs have until recently remained unexplored. However, in order to achieve the vision of electronic collection, processing and re-use of health data throughout its lifetime cycle while ensuring the fulfillment of interoperability requirements, e-enabled registries need to be included as a target of national eHealth agendas,

thereby establishing the link with ongoing EHR initiatives.

Organisational aspects — registries' operations and procedures

Researchers' access to classified registry data has generally been quite complicated and time consuming starting with locating appropriate data, preparing research applications and on to requesting permissions and negotiating data transmissions or access rights. Each one of the steps in this process can take a variable length of time and incur widely differing costs, depending on the registry holding the data in question. Both elements though may turn into considerable barriers, particularly from the perspective of socially and politically urgent research work. New solutions of more straightforward application processes and remote access to data are being developed.

Procedures for granting access to or sharing data in a cross-border context must be in place, preferably including predefined response time targets. An organizational culture oriented towards, as well as appreciative of data utilization beyond its own remits, combined with appropriate resourcing are essential elements in achieving a high level of preparedness. Collaboration with other registries' holders is advisable, in order to exchange experiences, advice and ideas.

Open data is an overarching idea which stretches to cover parts of classified data in the form of metadata. Openly publishing the content information of limited access systems would boost the efficiency of scientific research, enhance the quality of results, increase transparency and help create new research ideas.

Legal aspects

The most important European law affecting patient registries' operations is the Data Protection Directive (95/46/EC) that regulates the collection, processing and distribution of personal data. Registry holders should always be aware of the basic notions and effective norms of Data Protection, as securing privacy of the research subjects is a fundamental task when establishing and maintaining a patient registry. Currently the implementations and interpretations of the Data Protection Directive vary between Member States. Additionally the roles of Ethical Committees and data protection authorities vary a lot. The legislative process toward the new harmonizing Data Protection Framework is still unfinished. Moreover, the European Union Directives and Regulations considering Medical Devises, Pharmacovigilance, Clinical Trials and Cross-Border Health Care induce new information needs that will increase demand for patient registry data. Registry holders should actively follow the ongoing overhauls of the aforementioned laws.

By and large a patient registry can be established using either of two legal instruments; by explicit consent of the data subject, or based on law. Current practices among the EU Member States registry holders' surveyed by PARENT appear to be almost equally divided between the two models. The final content of the forthcoming Data Protection Regulation will play a decisive role in the choices available for registry establishment and operations in the future.

Adoption of a consent model presumes thorough planning of the purposes of the registry. The required content of informed consent varies between Member States. That's why it is important to consult local data protection authorities or ethical committees in the process of formulating the consent model. The European Data Protection Working Party (WP 29) has given an opinion regarding the definition of consent (WP 29, 2011). The Opinion provides a thorough analysis of the concept of consent as currently used in the Data Protection Directive.

According to the existing Data protection Directive Article 2.h »the data subject's consent« means any freely given, specific and informed indication of his/her wishes by which the data subject signifies his/her agreement to personal data relating to him/her being processed. The definition of the Directive implies an opt-in strategy of the consent. For the legal protection of the registry holder and patient, it is advisable that the consent is

given in written form. If personal data is transferred abroad, this should be communicated in the context of acquiring informed consent.

Even though the European Commission has proposed a Regulation as a substitute for the existing Directive, it is also likely that some national legal variation regarding patient registries will continue to exist. These disparities reflect differences in Member States' national health care systems, information infrastructures and legislations. Thus, it is always important to consult regional or national data protection authorities or ethical committees when establishing a registry.

The generalized interpretation has become that even encrypted and pseudonymous data are personal data. That is why it is pivotal to understand the basic notions regarding personal data in order to understand the areas where Data Protection Rules are applicable. Registry holders and data processors should always be able to differentiate clearly the notions of pseudonymous data, encrypted data, anonymised data and aggregated data.

It is likely that the upcoming European Data Protection Framework will require more transparency and accountability from patient registry holders. Generally it is advisable to be open about the registration purposes and give clear information to maintain public trust and credibility of patient registries. This involves ethical and well-structured informed consent practices, as well as maintaining clear and open descriptions of the registry and its metadata online.

Securing privacy of the research subjects is a fundamental task when establishing and maintaining a patient registry. The generalized interpretation has become that even encrypted and pseudonymous data are personal data. That's why it is pivotal to understand the basic notions regarding the personal data in order to understand the areas where Data Protection Rules are applicable.

According to the Data Protection Directive, personal data means any information relating to an identified or identifiable natural person (»data subject«). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

The current Data Protection Directive does not define the often used concepts of pseudonymous data nor encrypted data. According to European Parliament's proposal given in March 2014, pseudonymous data means personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution. According to the same proposal encrypted data means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorized to access it (European Parliament 2014).

It is notable that according to these definitions both pseudonymous data and encrypted data are considered to be personal data. Therefore the Data Protection Law applies to them.

Anonymised data means data in which all identifiers have been removed so that there is no reasonable possibility to link data back to individual persons to whom data relates and no code key exists to link the data to persons. Anonymised data are not personal data as the data has been altered so that the data subjects can no longer be identified. The possibility to re-identify data subjects must be considered on a case-by-case basis. For example, the deletion of names and personal identity numbers is often not sufficient to make data anonymous. Complete anonymity requires that the possibility for both direct and indirect identification is removed and that the code key is destroyed.

Aggregated data means statistical data on individuals that has been combined to show values without possibility to identify individuals within the aggregated data set. One practice has been to share and hand over aggregated or anonymised data in order to eschew the data protection norms. Often however, that is not possible as the analysis requires sharing

of individual level data whether it is in encrypted or pseudonymous form.

The Data Controller of the Patient Registry should always be defined unequivocally. Data Controller, according to Data Protection Directive, means the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data. Where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national or Community law.

Data Processor, according to the Data Protection Directive, means a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller. Third party means any natural or legal person, public authority, agency or any other body other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor, are authorized to process the data. The recipient means a natural or legal person, public authority, agency or any other body to whom data are disclosed, whether a third party or not.

Semantic aspects

Operating in an international environment or readiness to do so requires that solutions regarding linguistic barriers have been thought of and implemented — both at the level of data and at the level of generic information necessary for data sharing (e.g. information on procedures for access to data, application forms etc.)

The comparability and transferability of health data across languages and contexts of use is heavily dependent on the adoption and use of accepted coding standards.

Metadata is »structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information source«. It is meant to describe the phenomenon it concerns, and also document its changes over time. Good quality metadata is vital for data utilization. To make datasets comparable and useful for other users and between registries, metadata should be standardized according to validated and widely used classifications. Another aspect of standardization is recording metadata elements in the register's information model. That is, to make standardization as complete as possible, it must also cover data architecture and programming details.

When establishing and maintaining a registry, it is pivotal to identify the relevant stakeholders and generate a cooperation structure within them. The key stakeholders from the registry holders' perspective are usually health care professionals, patients, pharmaceutical and medical devices industry, ICT-suppliers, policy makers, researchers and other registries. If taken further, the opening of detailed metadata in standardized format would ease the registries' multi-stakeholder cooperation as well, particularly in the cross-border setting. The first step in opening registry metadata could include basic information about the data, such as description, owner, information content, target group, update intervals, dependencies from other data etc. preferably on the basis of agreed standards. This kind of increased visibility and traceability of health data collections would benefit patient registries and lead to new ideas and innovations. Joining yellow-page type services like the PARENT Joint Action Registry of Registries (RoR), the AHRQ Registry of Patient Registries (RoPR) or other specialized »umbrella« registry is a concrete implementation step and opportunity for identifying further areas for targeting development efforts.

As open data has recently gained importance also on state administration level (e.g. the British government's »opening up government« initiative and the Finnish Ministry of Finances' »open data programme«), open data and the possibilities it may yield must be carefully considered in the patient registry environment. Firstly, a line must be drawn between the data which can be opened given the technical, and, above all, data

security restrictions, and the data which cannot be opened (such as patient registries' microdata).

Technical aspects—guaranteeing shareable data

There are different levels of implementation for to the technical solutions required, starting from the choices made on the level of an individual registry and up to the level of platforms for cross-border sharing of data. It is not the purpose of these guidelines to take a stand in advising for or against the use of specific technological solutions, since these are both context-specific and a constantly moving target as new technologies emerge. However, the technical layer is crucial in ensuring the ›shareability‹ of health data and hence adopted solutions must be such that take into account and support regional/national infrastructures and semantic requirements for patient data collected in the process of healthcare services provision.

On the level of technical operationalization of legal requirements, particularly in terms of data protection and safety, adopted solutions must be robust and reliably proven to perform the expected tasks.

Effective and sustainable solutions for cross-border registry collaboration

The creation of effective and sustainable solutions for the cross-border use of registry data is a process where all the aforementioned requirements must be concertedly brought to the play in order to serve clearly defined unique targets, such as those explored in the PARENT Joint Action Scenarios (Reference). The added value generated by achieving these targets will act as the key driver for the engagement of stakeholders who in turn can guarantee the sustainability of the required cross-border registry infrastructure and operation environment, a subject discussed in detail in the respective PARENT Joint Action report (Reference to Business Models and Sustainability).

Project management team

The involvement of a person skilled and experienced in project management is advised. If this is not possible, it would be worthwhile considering training for a project manager and consideration given to the use of project management software.

Scientific committee

The aim of the scientific committee should be to ensure that the registry is outcomes driven and that data collected is disseminated effectively. It is suggested that the committee aim to meet four main objectives:

- Question identification
- Data element identification and selection
- Dissemination of results
- External data access/study proposal adjudication

As such, this group should consist of subject matter experts, ideally with a track record in publication of scientific results. It would also be ideal to include members of the group with statistical/epidemiological and health outcomes analyses experience, so that these factors remain in focus throughout the design, implementation and life of the registry.

Based on the scope identified by the advisory board and the input of the stakeholder evaluation, the committee should identify specific questions that the registry will address. These questions will inform the selection of data fields that the Registry will record.

Data element identification & selection

It is suggested that this process be considered an iterative one that considers the dimensions of data quality discussed previously.

Statistical and Epidemiological analysis

This process is vital to ensure that the registry is developed to an appropriate scale that ensures the purpose and objectives it was created for are met.

Extra data fields add considerable complexity and cost because of data validation requirements. A statistical analysis can help highlight the essential fields for registry success and help maintain

as much simplicity as possible; reducing the resources required ensuring completeness of data entry when the registry is implemented. It will also reduce the effort required to validate and analyse data. It is advisable that this process is conducted by statisticians and epidemiologists trained in registry science. If the registry development group has no formal attachment with experts with skills in this area, it is worth checking with universities or other registry groups, who might identify relevant experts.

Dissemination of results

Dissemination of registry data increases the potential impact of a registry and facilitates peer review. This process enables registry methods and data to be independently scrutinized, which in turn can validate the quality of the registry. Planning how registry data will be disseminated can help develop a timeline for implementation as well as ensuring that adequate funding is considered for this purpose.

External data access / study proposal adjudication

If a registry collects high-quality data, it is both likely and desirable that external requests will be received requesting access to data or proposing studies that can utilize registry data. To ensure transparency and facilitate best use of data, it is suggested that the scientific committee establish a formal plan to adjudicate on such requests. This might involve defining the grounds for collaborative agreements where external parties, in addition to gaining access to data, can benefit from the experience and expertise of committee members aware of the context in which the data was collected.

The full document »Methodological guidelines and recommendations for efficient and rational governance of patient registries« is available on the website http://www.parent-ror.eu.

KEY FACTS

- Duration: 36 months (2016–2019)
- Total budget: about EUR 3.6 million
- Programme: Interreg Baltic Sea Region
- Fund: European Regional Development Fund
- Flagship project of the EU Baltic Sea Region strategy

PROJECT PARTNERS

- Life Science Nord Management GmbH (Germany; Lead Partner)
- Stryker Trauma GmbH (Germany)
- University Medical Center Schleswig-Holstein (Germany)
- University Medicine Greifswald (Germany)
- Sahlgrenska University Hospital (Sweden)
- ScanBalt fmba (Denmark)
- Lithuania University of Health Sciences (Lithuania)
- LifeScience Krakow Klaster (Poland)
- University Hospital in Krakow (Poland)
- University of Tartu (Estonia)
- Tartu Biotechnology Park (Estonia)
- Bone Index Finland Ltd. (Finland)
- BONESUPPORT AB (Sweden)

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