

BFCC

Sustainability Concept

Anna Eckers, Imke Schneemann, LSN

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Preamble

- This concept was developed to support the sustainability of the **Baltic Fracture Competence Centre BFCC**.
- In this concept, the term "BFCC" refers to the permanent organisation. The term "BFCC 1.0" refers to the project from 2016-2019 and "BFCC 1.1" refers to the extension from 2019 to 2021.
- The concept includes a model for the **organisation and financing of the BFCC** based on the established **Transnational Fracture Registry Platform TFRP**. It includes the procedure of **data access**.
- The concept shows a possibility to **include further hospitals** into the TFRP within the countries involved in the consortium and into further countries within the BSR. It provides standards and supports the establishment, implementation and operation of individual fracture registries in new hospitals.
- The concept describes how industry* benefits from the TFRP, e.g. from innovation reports.
- The documentation of the sustainability concept was created in the form of a presentation in order to concentrate on the essential key points and to **facilitate the discussion** about the sustainability concept between and within the partner organisations.
- This concept should also be the **basis for future involvement** of further hospitals and securing investor financing.

Content

Hereafter, these aspects will be considered:

- BFCC 1.0 project overview
- BFCC 1.0 project results
- BFCC 1.1 extension stage
- BFCC vision
- Questions to be answered after 2019
- BFCC mission
- Future BFCC overall structure
- BFCC management unit
- Fields of activity
- Costs
- Development phase
- BFCC association
- Contracts
- Cash flow
- Target groups
- Options legal status
- Financing
- Timeline

BFCC 1.0 Project in a nutshell

Baltic Fracture Competence Centre

- Interreg Baltic Sea Region Programme 2014-2020
- Duration: 36 months (2016 – 2019)
- Total budget: EUR 3.6 million
- Flagship project of the EU strategy of the Baltic Sea Region
- Lead Partner: Life Science Nord Management GmbH
- 13 organisations from 7 countries round the Baltic Sea





BFCC 1.0 Project partners

- Hospital // Existing fracture registry**
Sahlgrenska University Hospital, SE
- Hospital // Novel fracture registry**
Lithuania University of Health Science, LT
University Hospital Krakow, PL
University Medical Center Schleswig-Holstein, DE
University of Tartu, EE
- Industry**
Bone Index Finland Ltd., FI
BONESUPPORT AB, SE
Stryker Trauma GmbH, DE
- Research institution**
University Medicine Greifswald, DE
- Cluster**
LifeScience Klaster Krakow, PL
Life Science Nord Management GmbH, DE
ScanBalt, DK
Tartu Biotechnology Park, EE



BFCC 1.0 objectives and solutions

Fostering innovation for better fracture management



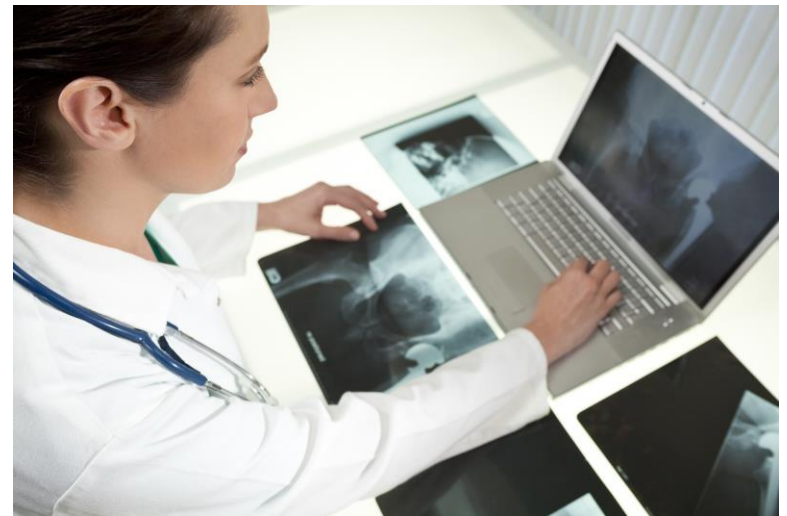
Project objectives

- Establishment of a transnational registry platform
- Establish a research and innovation network within fracture management
- Collection of clinical data in and analyse from transnational registry
- Foster hospital-industry cooperation for new product and service development



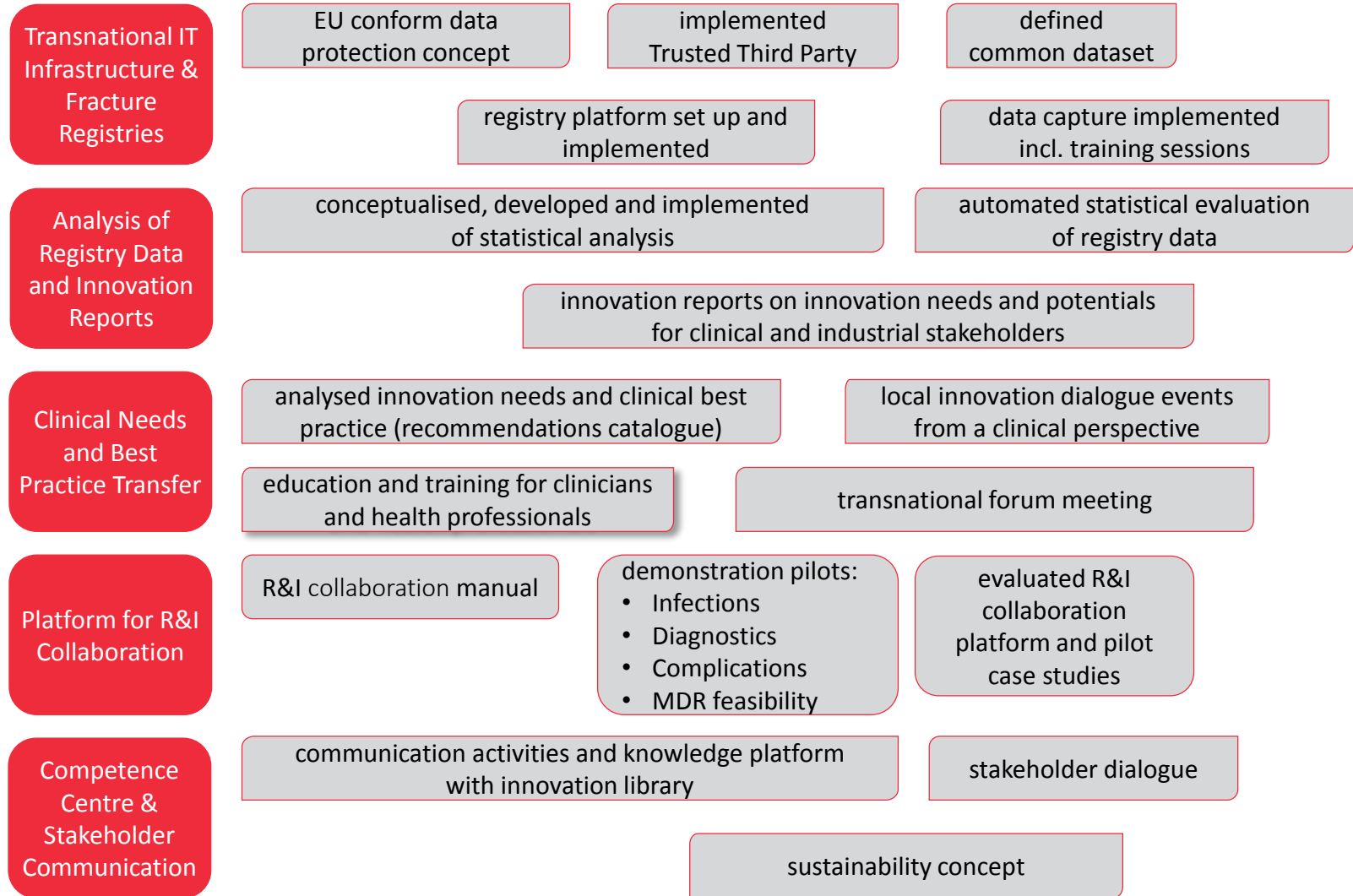
Desired improvements

- Improve health outcome
- Reduce hospital stay
- Strengthen competitiveness and support growth of BSR companies
- Answer research questions about fracture-related complications etc.



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BFCC 1.0 work packages and outcomes

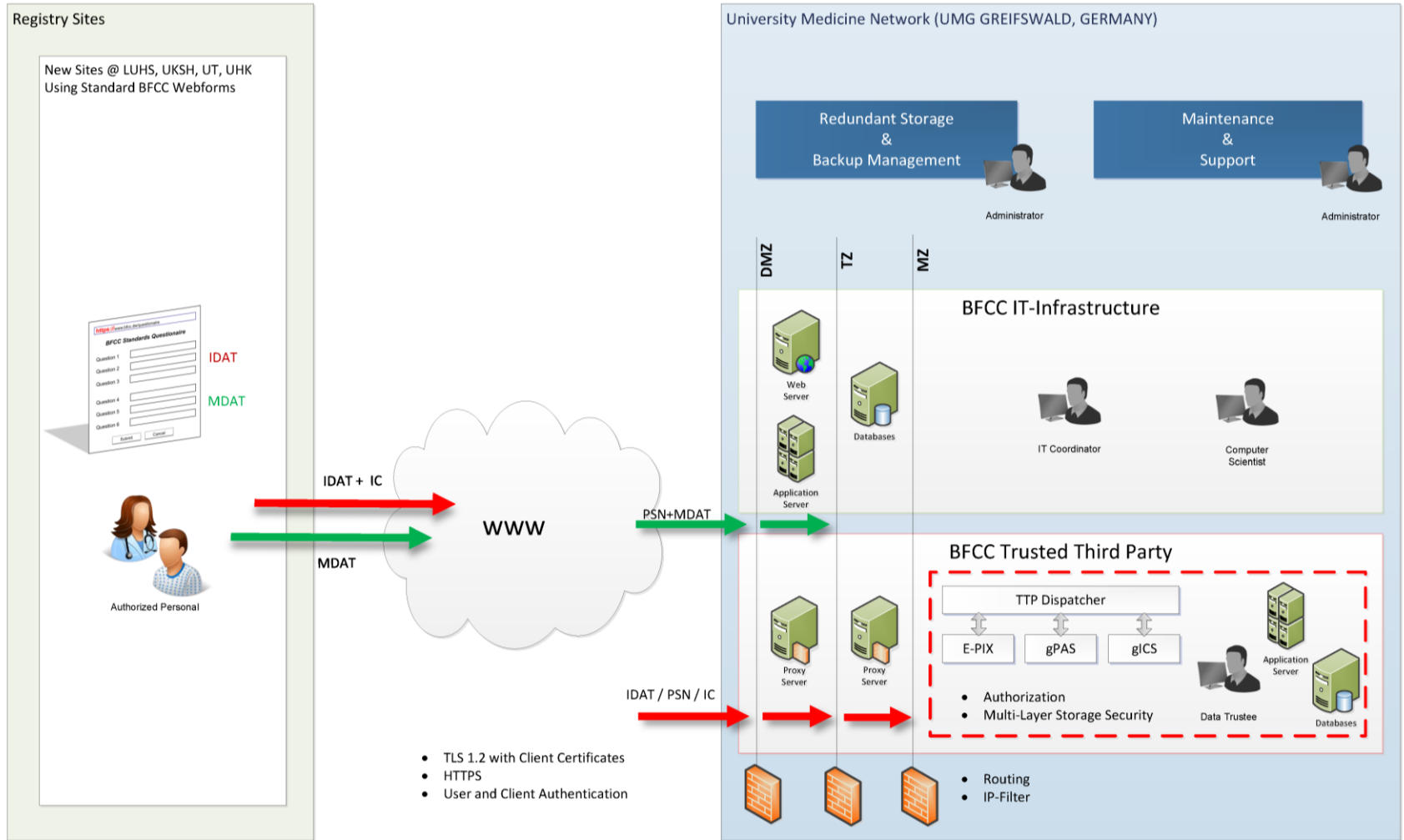


BFCC 1.0 project results 2019

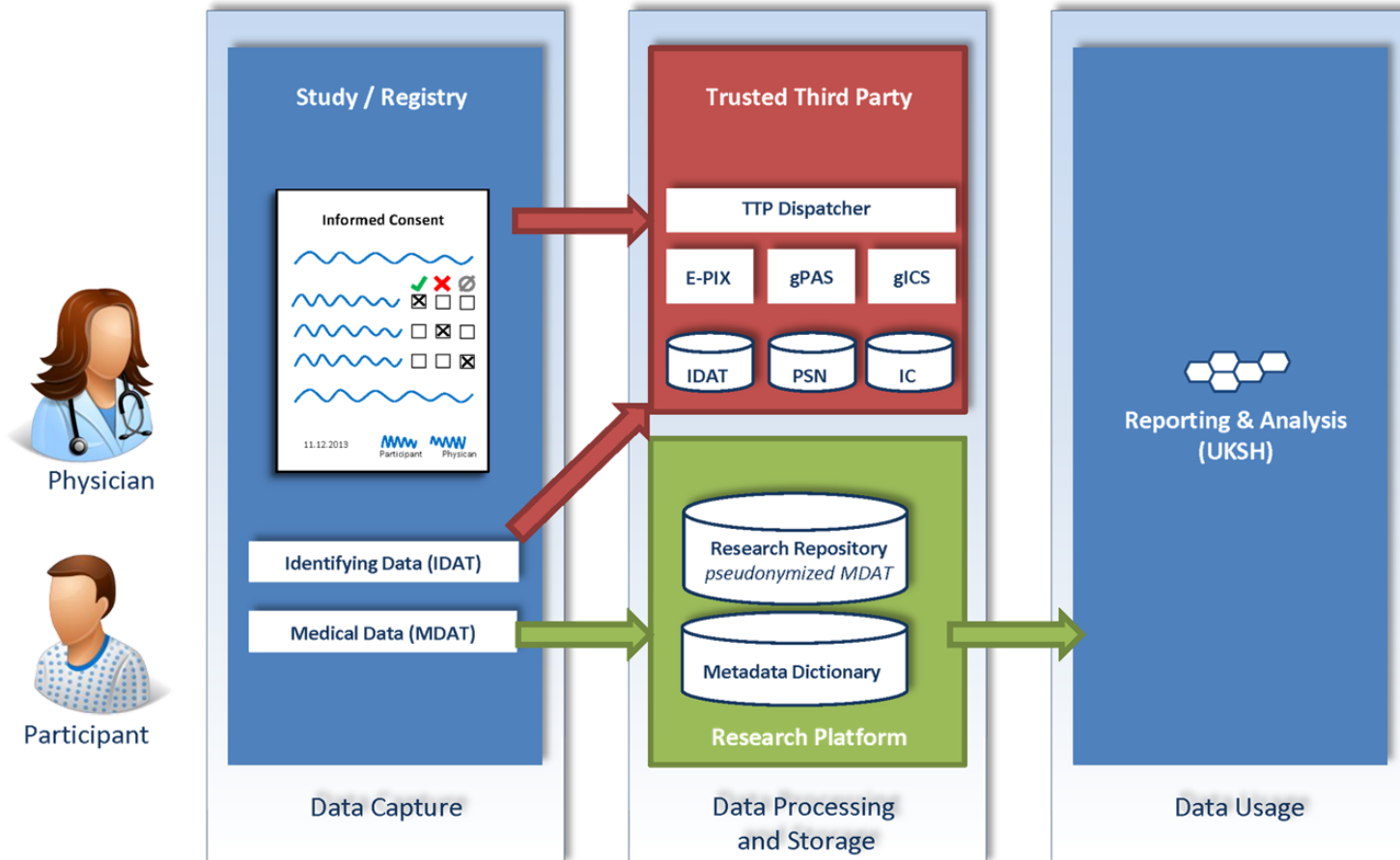
The BFCC 1.0 project results at the beginning of 2019 are:

- Transnational fracture registry (data from DE, EE, LT, PL)
 - Data protection concept in line with EU and national law
 - Minimal dataset
 - Defined data capture processes
 - Data access concept
 - Training concept for the fracture registry sites to enter data
- 2 innovation reports
- Best practice education and training concept for clinicians
- Concept for transnational cooperation between hospital and industry
 - Results from 3 pilots to line the concept
- BFCC cooperate identity and website including knowledge platform
- Stakeholder network

Registry IT infrastructure



Separation of powers using a Trusted Third Party



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Based on: Bialke, M., et al., A workflow-driven approach to integrate generic software modules in a Trusted Third Party Journal of Translational Medicine, 2015. 13(176).

Data ownership and usage

- Health information is one of the specific types of personal information and, as such, is particularly protected by privacy. Patient data may only be collected, stored, used and processed under strict conditions. It regularly requires the consent of the person concerned. The transmission of patient data to third parties is permitted only in a few exceptional cases and requires either the explicit consent of the person concerned or a legally determined permission.
- The patient is admitted to one of the hospitals involved in BFCC. When the patient signs the BFCC patient consent form, his/her data will be transmitted from the hospital to the BFCC registry. Owner of the data is the patient. The hospital and the BFCC registry have defined usage rights as long as the patient does not revoke them.



Training concept

- All newly connected hospitals will receive a training in form of a webinar by the IT infrastructure operator how to use the TFRP.
- Based on an example patient, the data are entered in the system. First the person-identifying data via the Trusted Third Party, afterwards the medical data via the data collection system. This procedure serves as a test run for real medical cases to be raised, so that the user can develop a sense of the system. In addition, the webinar provides the opportunity for study staff to ask questions.



Connecting further hospitals in the future

- The project consortium prepared an information sheet and has contact further hospitals in the Baltic Sea Region that are interested in the BFCC registry.
- A video on www.bfcc-project.eu demonstrate how to get access to the BFCC



Vision BFCC 2022

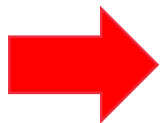
In 2022 BFCC:

- is “the” fracture register platform in Europe, with open database structure and standardized communication based on IHE
- already contains a large number of high quality data (completeness is crucial).
- has additional hospital partners entering data into the transnational registry.
- is a tool for hospitals for quality assurance.
- supports industry regarding MDR activities via the transnational registry.
- provides high quality data.
- provides prepared information on basis of high quality data.
- provides a basis for high impact publications.
- is an information hub for innovation in the field of fracture management.
- supports companies by providing a better insight into the “fracture” market
- is an accelerator for cooperation between industry and hospitals.

Mission of the future BFCC organisation

The mission of the future BFCC organisation is to ensure:

- that an optimal structure for the future BFCC will be created.
- the entry of high quality data.
- added value for hospitals regarding quality assurance.
- that clinicians/hospital managements understand the added value of a TFRP.
- the connection of further hospital partners entering data into the TFRP.
- responding to signals from users.
- execute scientific studies using the TFRP.
- that impact publications could be prepared.
- the provision of high quality data to interested parties.
- support industry by identifying needs and potentials for innovation
- the support of industry regarding MDR activities.
- strengthening the competitiveness and supporting the growth of BSR companies.
- that BFCC is an information hub for innovation in the field of fracture management.
- that BFCC is an accelerator for cooperation between industry and hospitals.



Implementation of the sustainability concept

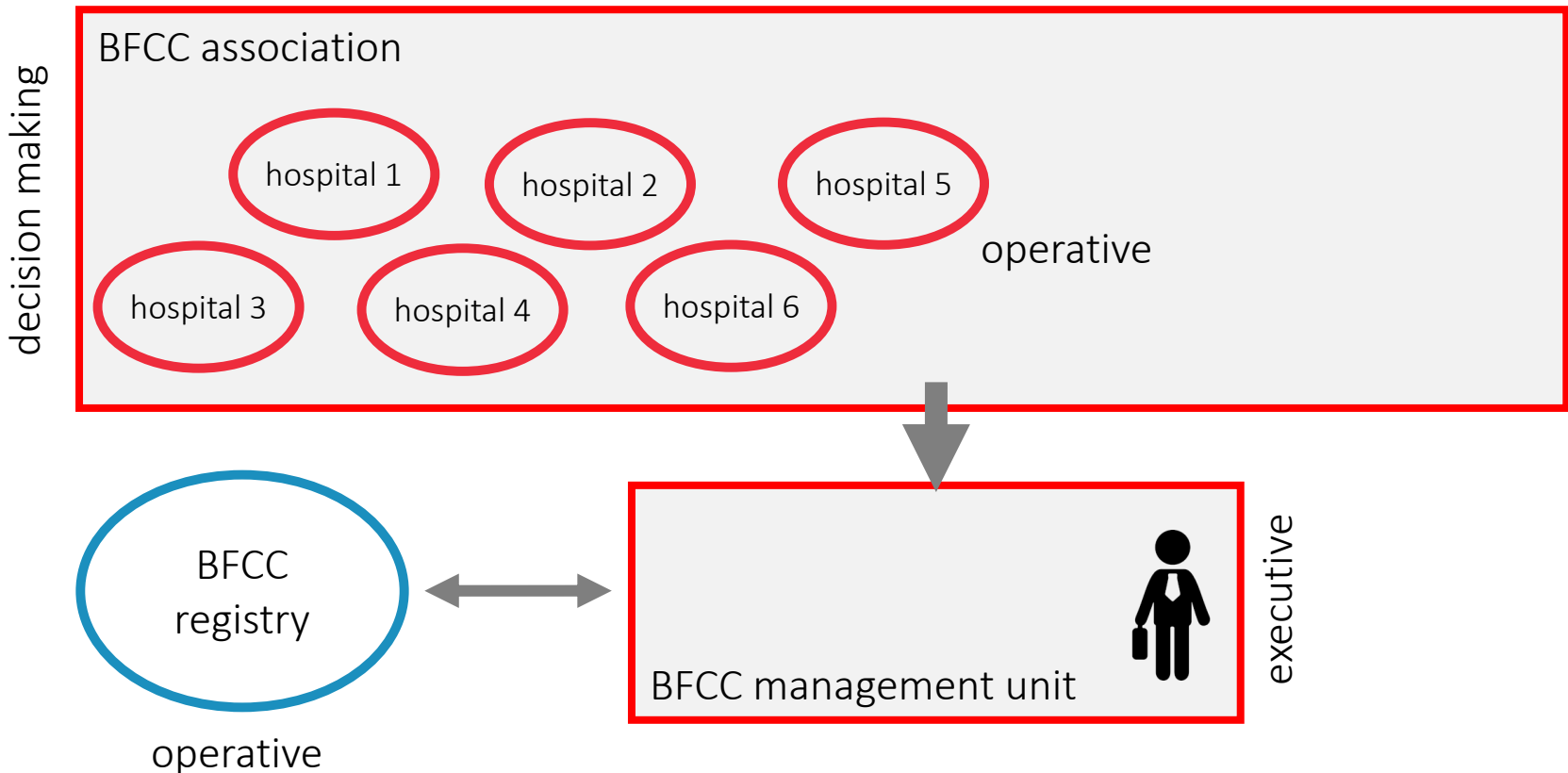
BFCC 1.1

The BFCC 1.1 will consist of a BFCC management unit and a BFCC association. The BFCC management unit is the operative entity and will be responsible for involvement of further hospitals, preparation of reports and data packages, marketing, customer and stakeholder relationship management, facilitation of cooperation and for the cooperation with the BFCC registry, so to speak for all external relationships.

Hospitals being a BFCC transnational fracture registry site are part of the BFCC association. The association will comprise a steering group as well as a member assembly.

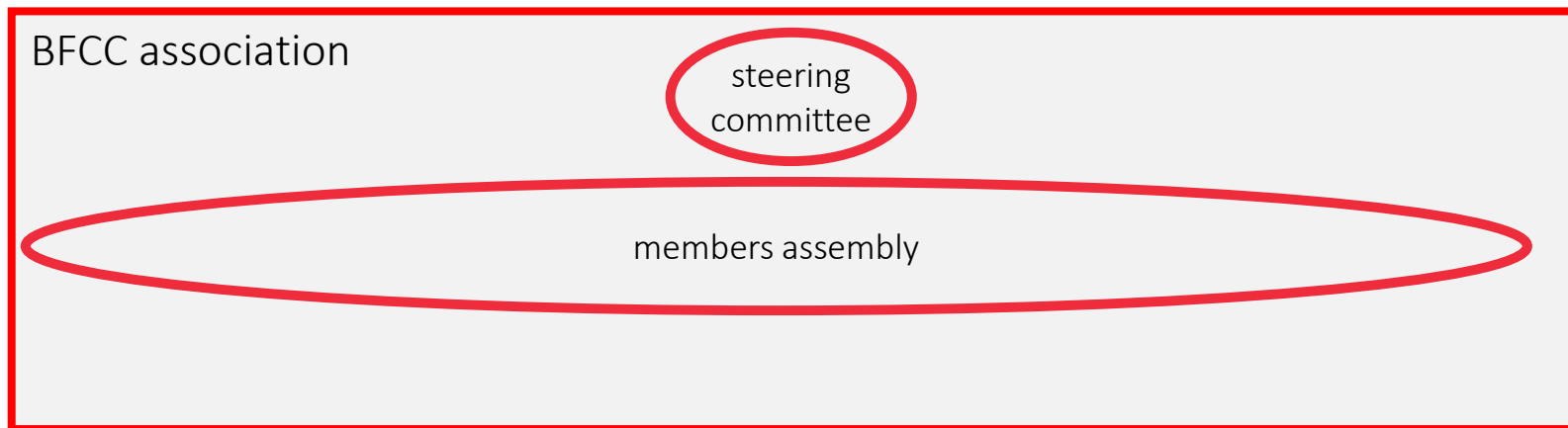
Future BFCC – the overall structure

BFCC management unit is the operative entity of the BFCC association.



BFCC association

- Members of the BFCC association are hospitals.
- The members assembly shall be the body by which the members take collective decisions. Those decisions shall then be implemented by the BFCC management unit.
- The members assembly shall be composed of all members of the BFCC association.
- Each member shall be represented by two delegates.
- The Steering Committee shall be responsible for supporting and monitoring the performance of the BFCC management unit.
- Each member shall be represented by one delegate.



Different kind of membership

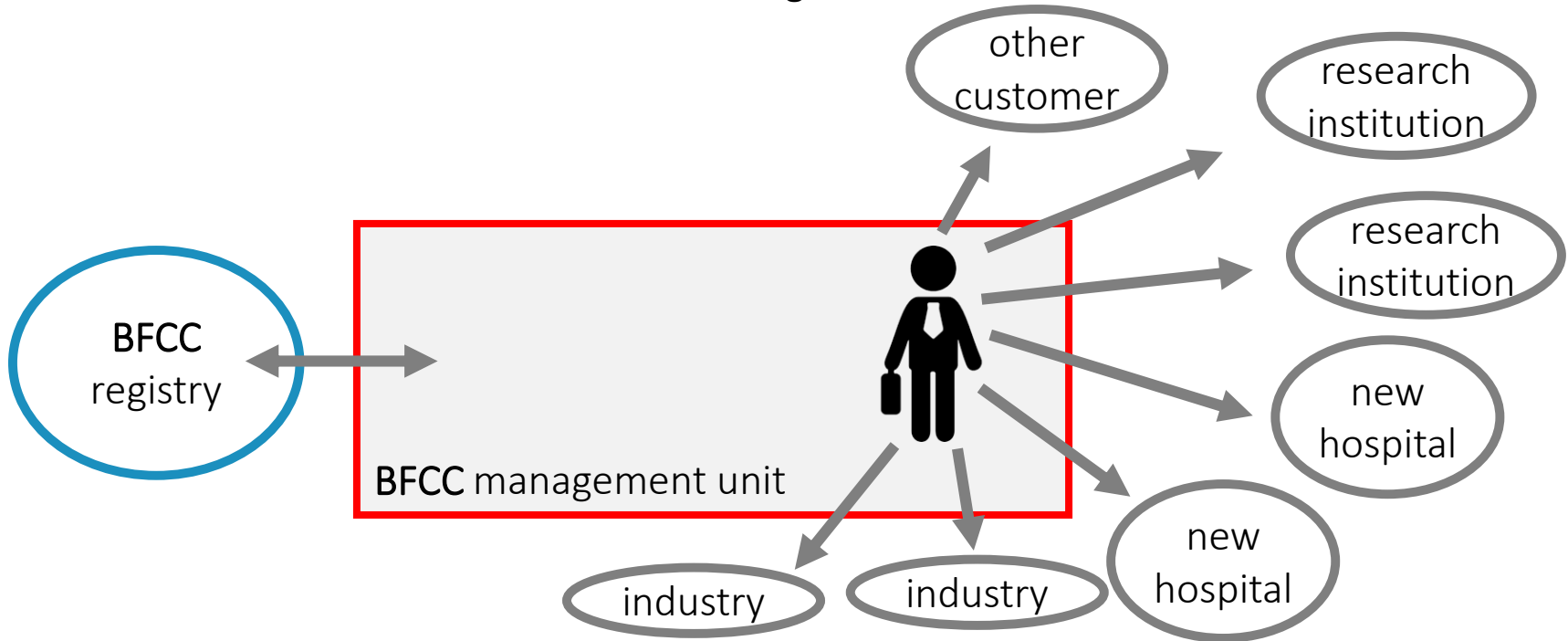


Different options in terms of data access

- Members entering a minimum number of data
- Members entering no/less data

BFCC management unit

The external relations of the BFCC management unit:



BFCC management unit from 2019 on

Service Portfolio

We verified the different options mentioned in the BFCC 1.0 application like online job exchange. Stakeholders are mainly interested in the use of registry and registry data as well as in an annual conference. Therefore,

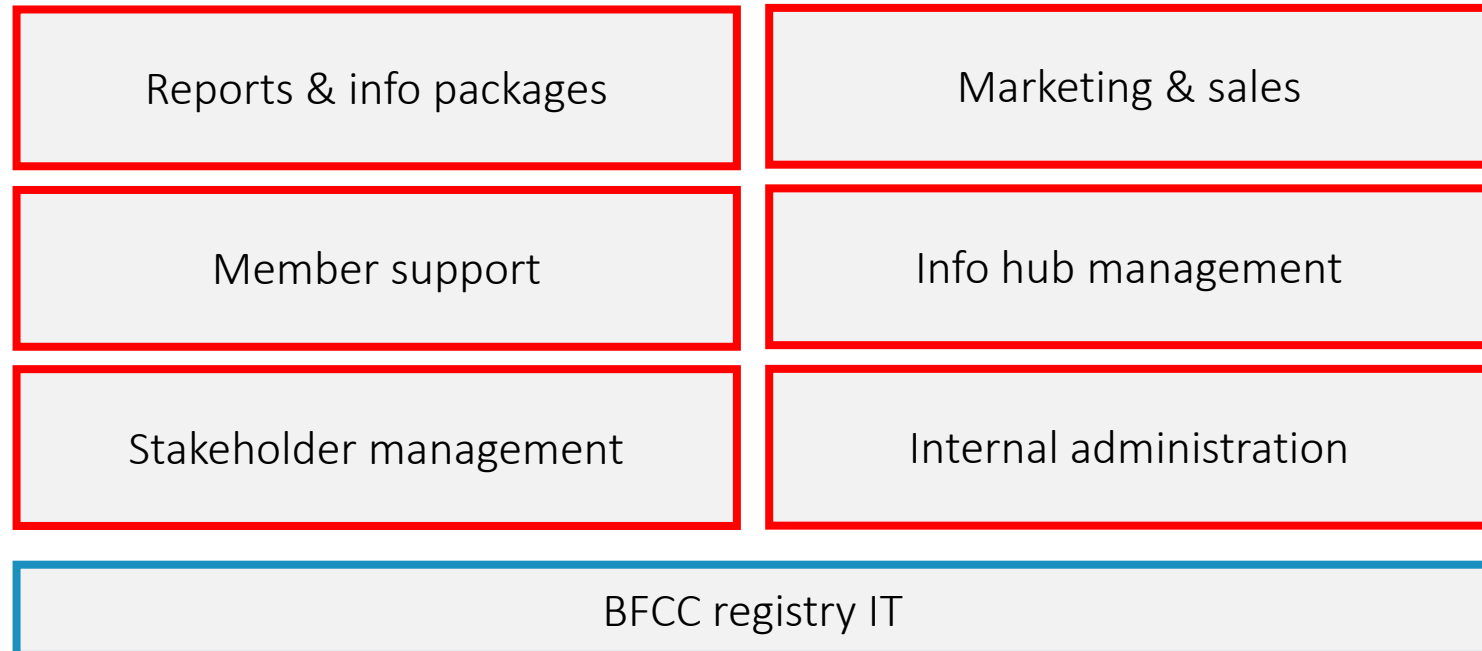
the BFCC Management Unit shall be the operational centre with the main mission:

- run the registry
- organize the analysis, preparation and provision of data and reports
- motivate clinicians to enter high quality data over a long period
- win additional hospitals
- win customers
- establish partnerships
- do PR and marketing
- acquire sponsors/financiers

Activity fields of the future BFCC MU + Registry IT



The BFCC management unit will implement the main missions by implementing the following seven fields of activity:



Activity field: Registry IT

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to gather high quality data from various hospitals in the BSR and provide hospitals and potential costumers as well as further stakeholders with data.

Registry related tasks

- Registry development (IT infrastructure)
- Data entry
- Data analyse
- Data provision
- Technical connection of new register sites
- Training

Registry related functions

- Tool for hospitals for external quality assurance



Activity field: Reports & info packages

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to bring an added value to the participating hospitals and to industry, and being a source of income.

Report and info packages related tasks

- Quality reports on 3-monthly basis for hospitals as members of the BFCC association
- Annual innovation report with adequate paying or subscription scheme to attract customers.
- In the future, individual info packages are requested by potential customers for a fee



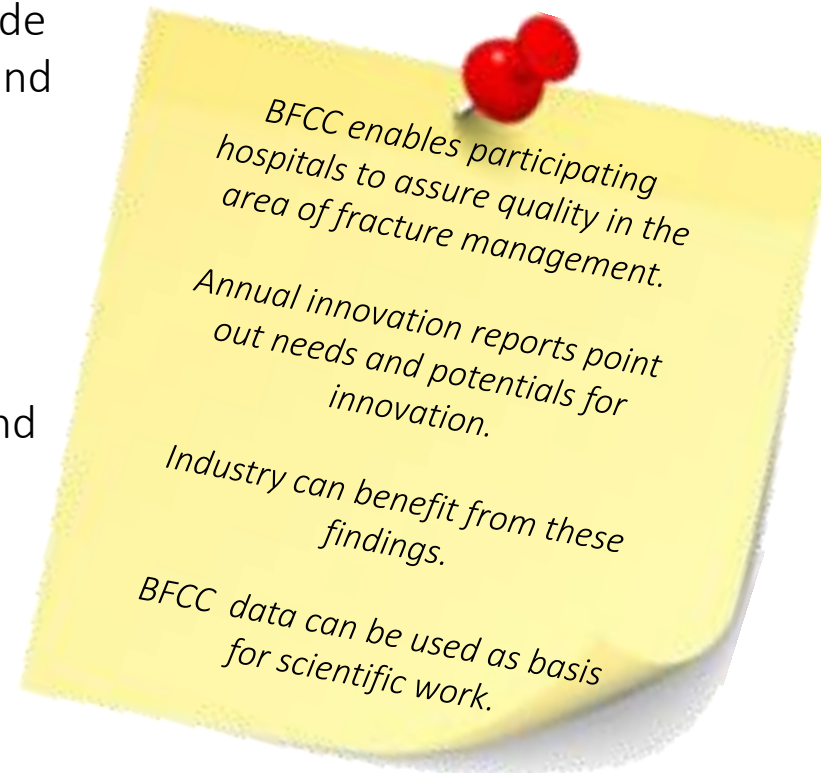
Activity field: Marketing & sales

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to provide information about the BFCC, raise awareness and promote BFCC innovation reports and data packages.

Marketing & Sales related tasks

- Attraction of new hospitals
- Customer acquisition (innovation reports and info packages for e.g. industry)
- Maintenance of the website
- Preparation of info material
- Event organization (annual conference)



Activity field: Member support

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to care about member satisfaction and comfort.

Member support related task

- Support of participating hospitals
- Conclusion of contracts with new hospitals willing to establish a new BFCC fracture registry site



Activity field: Info hub management

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to initiate and maintain cooperation between hospitals and industry and provide in-depth information about fracture management.

Info hub management related task

- Cooperation facilitation between industry and hospitals
- Mediation and facilitation of registry embedded clinical trials
- Enlarge information on website



Activity field: Stakeholder management

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

The main task of this field of activity is to position BFCC 1.1 and position BFCC 1.1 in associations and networks.

Stakeholder management related tasks

- BFCC as member in associations
- Dialogue with health insurances, financiers of public health care system, industry



Activity field: Internal administration

Reports & info packages	Marketing & sales
Member support	Info hub management
Stakeholder management	Internal administration
BFCC registry IT	

Internal administration related tasks

- Internal IT
- Human resources
- Accounting
- Controlling



Staff of the BFCC MU + Registry IT

Managing director <ul style="list-style-type: none">▪ Representation, jack of all trades, networker	Data analyst <ul style="list-style-type: none">• Compile data for requested info packages• Compile data for 3-monthly reports for hospitals• Compile data for annual report
Scientific / medical writer <ul style="list-style-type: none">• Literature & desk research• Finalize info packages (individual)• Finalize 3-monthly reports for hospitals• Finalize annual report	PR & marketing <ul style="list-style-type: none">• Bring BFCC in press• Develop info and marketing material• Maintain website• Prettify reports
Sales <ul style="list-style-type: none">• Win and bind new hospital sites• Win and bind new customers• Placement with associations• Lobbying• Apply for funding	Internal administration of the MU <ul style="list-style-type: none">• Accounting• Controlling• Human Resources• Office IT

Registry IT* IT administrator | Data protection officer | Quality manager

* Registry IT and MU don't have to be at the same place

Annual costs of the BFCC MU + Registry IT

A rough calculation for continuation of BFCC in its current condition

Managing director <ul style="list-style-type: none">▪ 0.5 FTE -> 40.000€	Data analyst <ul style="list-style-type: none">▪ 0.5 FTE -> 30.000€
Scientific / medical writer <ul style="list-style-type: none">• 0.5 FTE -> 30.000€ (outsourcing possible)	PR & marketing <ul style="list-style-type: none">▪ 0.5 FTE -> 30.000€
Sales <ul style="list-style-type: none">▪ 0 FTE -> 00.000€	Internal administration of the MU <ul style="list-style-type: none">▪ 0,5 FTE -> 20.000€

Registry IT*

Staff: 175.053 € | Hardware and software: 82.625 €*¹ | Maintenance, support and licences: 38.909 €
| Operating costs: 35.000 € | Travel: 12.500 €

FTE = Full time Employee

*1 incl. renewals every 5 years as annual costs calculated

Annual costs of the BFCC MU + Registry IT

a rough calculation of the estimated annual costs in Euro:

Office Costs

▪ Staff	150.000€
▪ Office + equipment	20.000€
▪ Travel costs	10.000€
▪ Marketing	25.000€
▪ Reports	20.000€
▪ Congress	40.000€

Register IT Costs

▪ Running the registry	344.087€
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-> 265.000€ + 344.087€ per year

Annual costs of the BFCC MU + Registry IT

An example calculation for a continuation of BFCC with 20 hospitals

Managing director <ul style="list-style-type: none">▪ 1.0 FTE -> 80.000€	Data analyst <ul style="list-style-type: none">▪ 1.0 FTE -> 60.000€
Scientific / medical writer <ul style="list-style-type: none">• 1.0 FTE -> 60.000€ (outsourcing possible)	PR & marketing <ul style="list-style-type: none">▪ 1.0 FTE -> 60.000€
Sales <ul style="list-style-type: none">▪ 1 FTE -> 60.000€	Internal administration of the MU <ul style="list-style-type: none">▪ 0,5 FTE -> 20.000€

Registry IT*

Staff: tbc | Hardware / software: tbc | Maintenance, support and licences: tbc | Operating costs: tbc

FTE = Full time Employee

Annual costs of the BFCC MU + Registry IT

a rough calculation of the estimated annual costs in Euro:

Office Costs

▪ Staff	340.000€
▪ Office + equipment	20.000€
▪ Travel costs	35.000€
▪ Marketing	50.000€
▪ Reports	20.000€
▪ Congress	40.000€

Register IT Costs

▪ Running the registry	tbc €
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-> at minimum 505.000€ per year

Future financing options

For the future BFCC two phases of financing are realistic.

1. During the development phase BFCC 1.1 (2019 – 2021) will be funded by third party funding (e.g. INTERREG BSR extension stage).*
2. From 2021 on the BFCC will be financed by:
 - Funding programmes
 - Member fees
 - Revenues through sale of innovation reports and info packages
 - Local, regional, national (health) authorities
 - Regional/national ministries
 - Sponsors
 - Health insurances, reimbursement
 - Donations

* The full costs as shown on the previous slides, arise only after 2021.

BFCC 1.1 Extension stage (2019-2021)

- The EU Interreg Baltic Sea Region Programme offers the possibility to apply for an extension stage project.
- The maximal duration of an Interreg **extension stage project** is **24 months**.
- The Interreg extension stage should be used to co-finance **the BFCC 1.1 development phase**.
- The project partners contribute with their co-finance contribution to the development of the BFCC management unit and the BFCC association in addition to other project activities.
- **The implementation of the BFCC Management Unit and its tasks should be one main part of the extension stage project** and hence one of the costs items.
- **The other project activities of the extension stage project will be defined until summer 2018**. E.g. one main part could be the definition of limited number of main research questions from each of the industry partners of the BFCC 1.1 extension stage project. These should be answered by the registry, to develop and implement the process of handling of such specific industrial research questions.

Development phase 2019-2021

In 2 years phase from 2019 until 2021 the BFCC management unit and BFCC association will be build up and implemented:

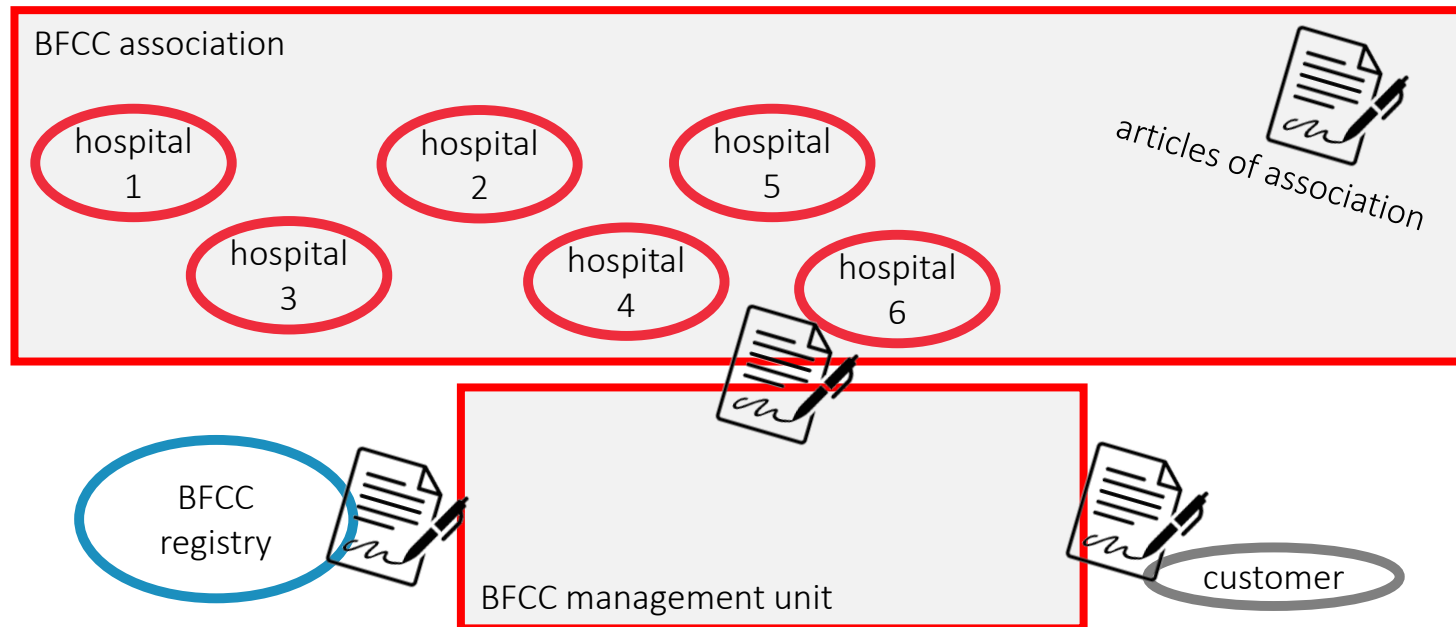
- implement legal form for the BFCC.
- clarify ownership of the TFRP.
- found BFCC association and BFCC management unit.
- ensure future financing of the BFCC / TFRP.
- motivate clinicians to enter high quality data.
- win additional hospitals as members.
- prepare four types of contracts.
- raise industry's interest in data and findings from TFRP.
- identify further industrial needs.

BFCC contracts

The implementation of the BFCC's services requires four types of contract, which will be developed during the BFCC development phase 2019-2021.

Between:

1. BFCC management unit and register
2. Hospitals entering data and BFCC management unit
3. BFCC association and BFCC management unit
4. BFCC management unit and customers



Target groups for the further development of the BFCC registry (I)

- **Hospital decision makers**

Hospital decision makers can decide if a hospital or parts of the hospital shall establish a fracture registry. They have the power to implement the duty for clinicians to enter data into the registry. The hospital management is interested in quality comparison and in positive marketing and reporting.

- **Clinicians**

Clinicians can convince their clinic management of added value. Senior clinicians motivate junior clinicians. Clinicians can monitor their quality of work. They could use the registry for clinical trials.

- **Researchers**

Researchers could use the BFCC registry for their scientific work and publish in high impact journals.

- **Industry**

Industry is a potential customer and could be interested in data info packages and reports. In addition, MDR requirements could be met via registry.

Target groups for the further development of the BFCC registry (II)

▪ Societies

Societies could be a place to promote the idea. Societies could award a label.

▪ Hospital associations

Hospital associations shall be convinced that establishing a fracture registry will improve the quality outcome of hospitals.

▪ Health insurances

Health insurances might be in the future more interested in registry data to support the choice of a hospital and could provide some kind of settlement.

▪ Local, regional and national authority

Local, regional and national authorities are interested in quality improvement of existing hospitals. They could also support the BFCC financially.



Two options for a legal form

According to our research, we propose two options implementing the BFCC association:

- Option 1: EEIG - European Economic Interest Grouping
- Option 2: ERIC - European Research Infrastructure Consortium

EEIG - European Economic Interest Grouping

Option 1 for the BFCC association

To found an EEIG is one option of a legal entity of the BFCC association. The main characteristics of an EEIG are:

- At least two members from different member states are able to found an EEIG. Members may be companies, universities, towns, counties, free lancers.
- As a minimum an EEIG must have at least two organs: 1) the members acting collectively (members assembly) and 2) a managing director.
- Apart from full members, it is possible to create the status of “associate members” via the conclusion of an “association agreement” stipulating voting rights and liability issues.
- The managing director has the power of sole legal representation.
- He/she is proposed at the EEIG’s constitution by the members’ assembly.
- No capital stock needed.

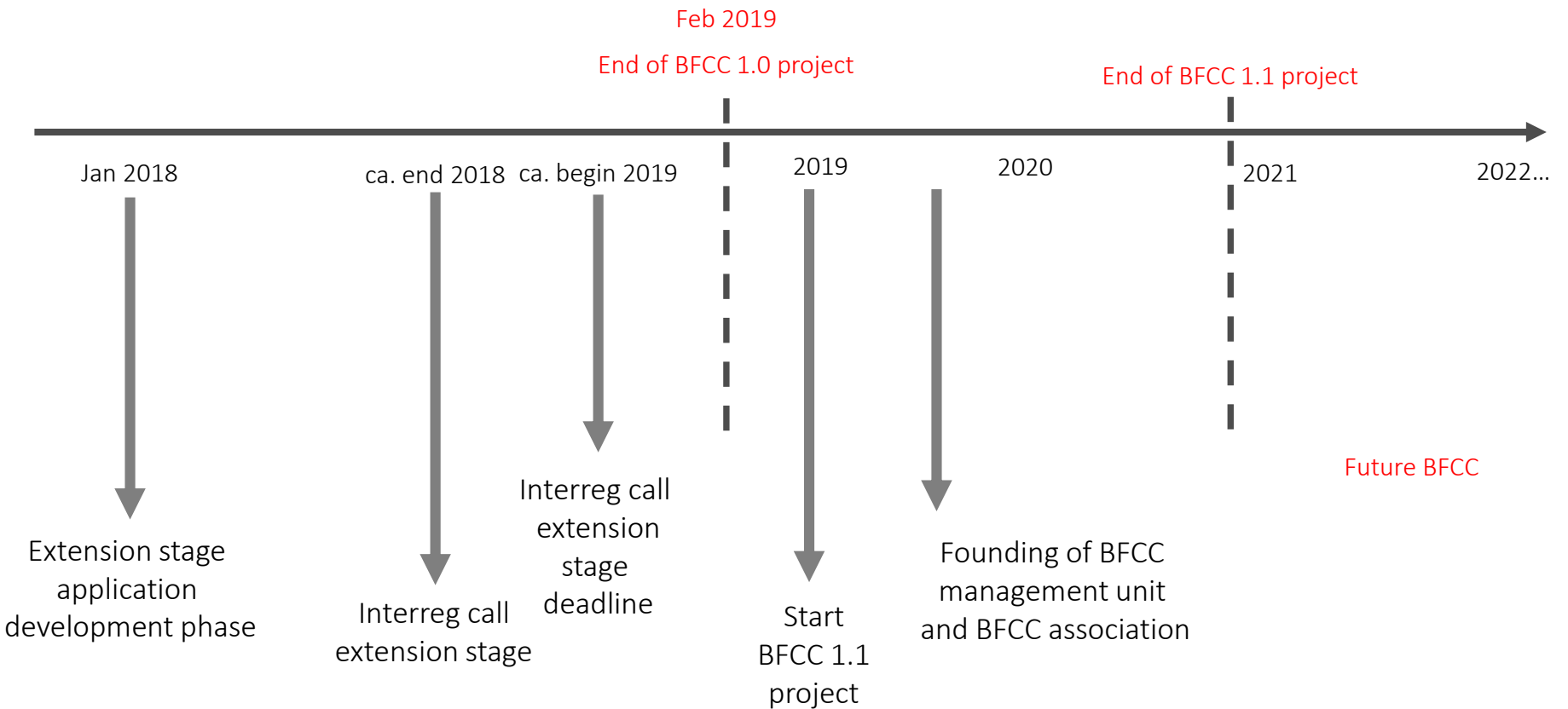
ERIC - European Research Infrastructure Consortium

Option 2 for the BFCC association

To found an ERIC is second option of a legal entity of the BFCC association. The main characteristics of an ERIC are:

- An ERIC is a full legal entity recognized in all EU member states. It requires membership of at least three states: one EU member state and two other countries that are either EU member states or associated countries.
- The objective of an ERIC is to establish and operate a research infrastructure of European importance on a **non-economic basis**. In order to promote innovation and knowledge and technology transfer, the ERIC should be allowed to carry out **some limited economic activities** if they are closely related to its principal task.
- Profit bodies may not be members of an ERIC.
- Financed by the countries who are members of ERIC (no funding by EU!). The ERIC is allowed to apply for external funding.

Timeline



Summary – the future of the BFCC (I)

- The BFCC has the vision to be “the” fracture register platform in Europe, to have 50.000 data entries of high quality, to have 20 hospital partners entering data into the transnational registry, to be a tool for hospitals for quality assurance, to support industry regarding MDR activities via the transnational registry, to provide high quality data, to provide prepared information on basis of high quality data, to act as an information hub for innovation in the field of fracture management, and to be an accelerator for cooperation between industry and hospitals.
- BFCC will be continued after 2019 in two phases: BFCC 1.1 phase (2019-2021) and the "BFCC" as a permanent organization from 2021 onwards
- Main scope of the BFCC 1.1 phase (2019-2021) will be the implementation of the sustainability concept developed in the BFCC 1.0 phase (2016-2019) to capitalize the results of the BFCC 1.0 phase
- In the BFCC 1.1 phase (2019-2021) the data input will be extended, more hospitals will be involved and customer relationships will be established.
- The BFCC partners will found a BFCC association as an ERIC or an EEIG.

Summary – the future of the BFCC (II)

- During BFCC 1.1. phase (2019-2021) a BFCC management unit will be established (in 2019) and developed as the operational centre of the BFCC association.
- The main missions of the BFCC management unit will be to organize the running the registry, to organize the analysis, preparation and providing of data and reports, to motivate clinicians to enter high quality data over a long period, to win additional hospitals, to win customers, and to establish partnerships
- Additional hospitals providing data will be involved from 2019 onwards through the BFCC association.
- 4 types of contracts to enter into binding agreements between the hospitals, the BFCC association, the BFCC management unit, the register IT, and customers will be created in 2019.
- Key success factors are the motivation of the project partners and the very good personnel selection of the BFCC management unit's employees.
- The BFCC 1.1. phase (2019-2021) will be financed third party funds (e.g. by Interreg BSR extension funds) and by the partners.
- From 2021 on the BFCC will be financed by different sources.