



BFCC

The BFCC Registry - technical implementation, data set and data entry

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Bone Summit, Lübeck

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Information Gap

- (How) can implant-related quality and adverse events be efficiently documented transnationally?
- Are there differences between countries regarding the frequency or kinds of complications?
- Which patient groups (e.g. age, gender, comorbidities, country?) are associated with what kinds of fractures?
- Which patient group is associated with increased complication rates?
- Can best practices be deduced from these differences?
- What are the benefits of bone substitute use for primary fracture fixation or complications treatment?
- Is Vancomycin in bone substitution efficient for infection prevention and infection treatment?

Aim and advantages of a Transnational Fracture Registry (TFRP) CDM approach

- each partner can access his/her own research data
- no delay between data entry and accessibility
- high level of data privacy and IT-security through establishment of an independent trusted third party
- central provision of real-time informed consent
- central data pseudonymization and storage
- data quality through continuous checks for plausibility
- each partner can request access to research data of partners / whole dataset
- reduced effort for all partners regarding IT-resources (staff-wise, organisational, technical)


Comprehensive Experience in Informed Consent- and ID-Management



Physician




Participant



GESUNDHEITS-STUDIE

Study / Registry



DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Informed Consent



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11.12.2013     Participant     Physician

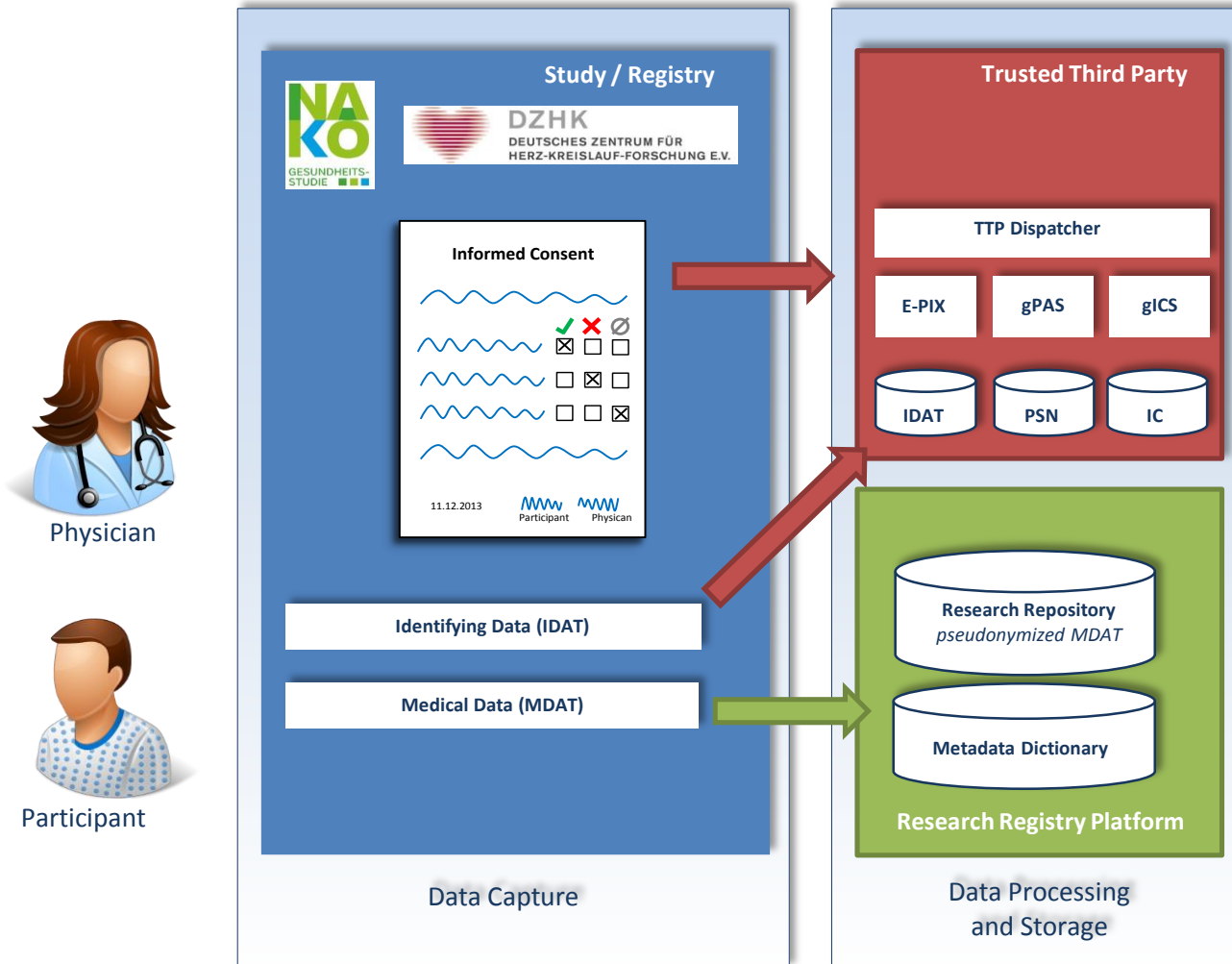
Identifying Data (IDAT)

Medical Data (MDAT)

Data Capture

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).

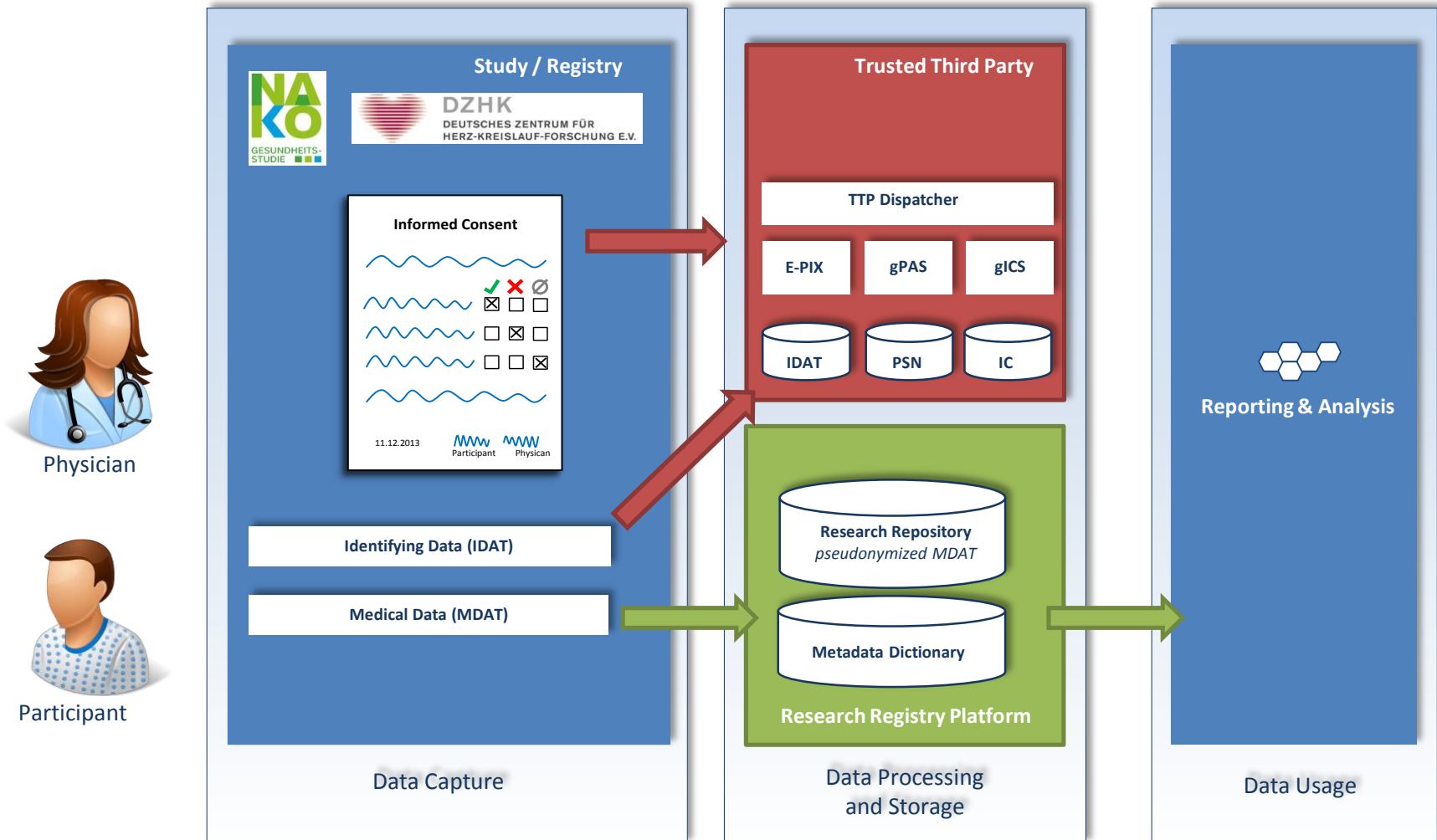
# Comprehensive Experience in Informed Consent- and ID-Management



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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).

# Comprehensive Experience in Informed Consent- and ID-Management

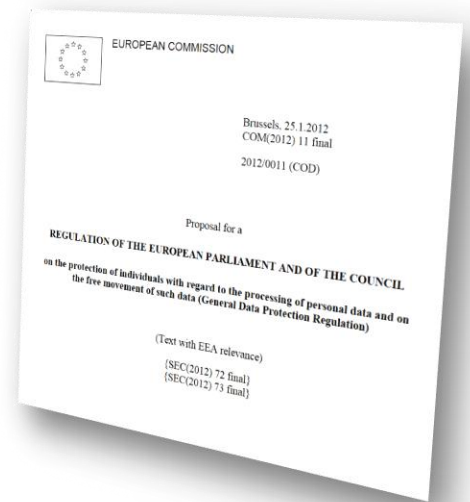


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Based on: Bialke, M., et al., **A workflow-driven approach to integrate generic software modules in a Trusted Third Party** Journal of Translational Medicine, 2015. **13**(176).

# Challenge

- EU General Data Protection Regulation by the European Commission
- mandatory for all EU-member states as of May 2018



## Aim: Assess legal terms for BFCC data management processes:

- (1) data capture procedures and
- (2) existing fracture data import (e.g. from Sweden)
- (3) transborder collection, storage, and transfer of person-identifying data (IDAT) and medical data (MDAT)

**Process:** a comprehensive legal report for the BFCC by DIERKS+Company

- conducted questionnaire survey to gather details on national and local data protection regulations in BFCC partner countries
- systematically evaluated legal dimensions of all CDM procedures including transborder transfer

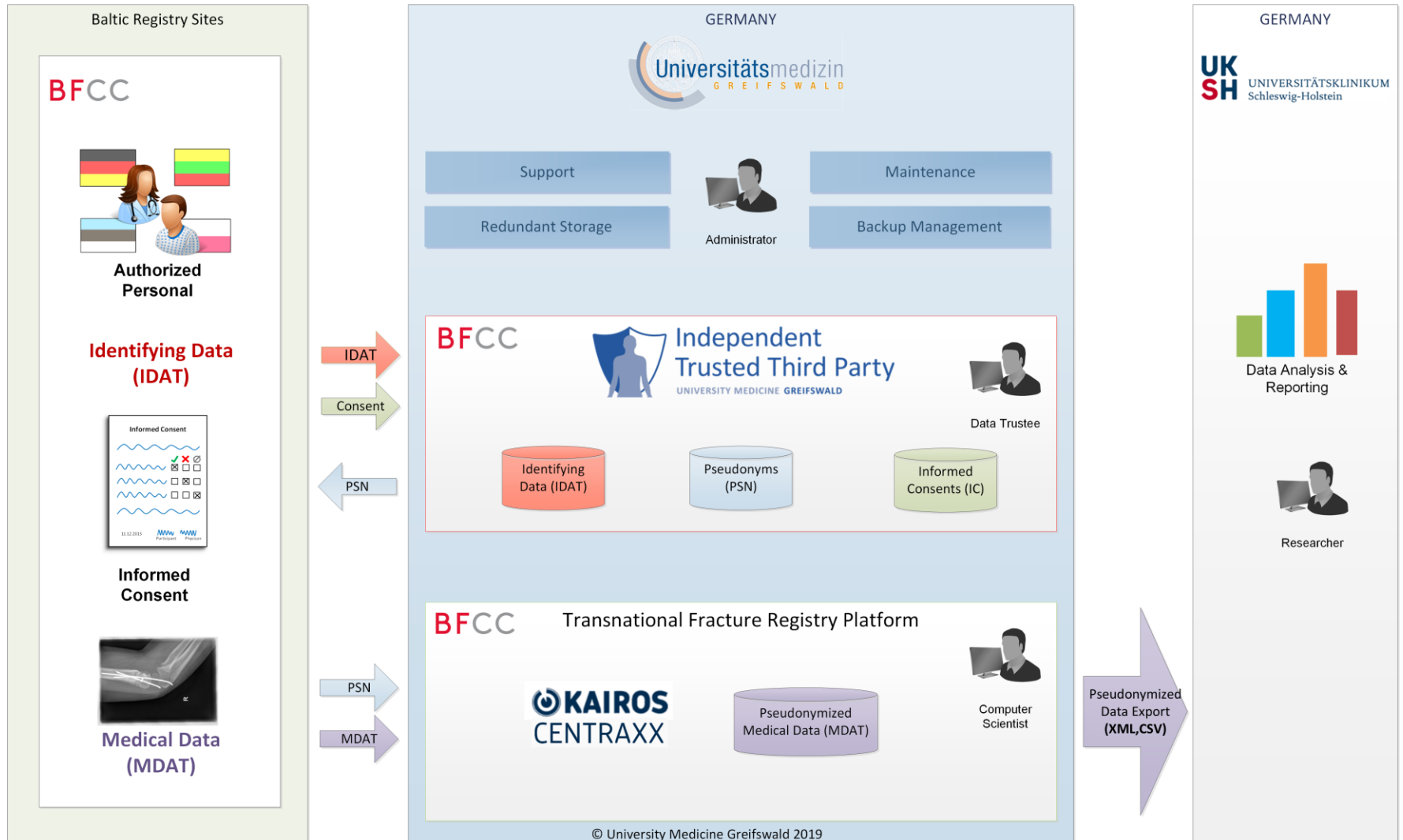
# Solution: Transnational Fracture Registry (TFRP)

## - Data protection by design

- Positive ethical votes for each BFCC site
- Uniform patient information and patient consent (English and country-specific translations) (*Art. 6 (1) GDPR*)
- Patients pro-actively consent to collection, storage and usage of his/her fracture data for predefined purposes within BFCC project (*Art. 6-11 EU-GDPR*)
- Central Trusted Third Party separately manages patients' identifying data (IDAT)
- Pseudonymized storage, transfer, and use of research data (*Art. 6 (4) GDPR*)
- Additional IT Security aspects: TLS1.2 with client certificates, IP-Filter, etc. (*Art. 25 GDPR and Recital 78 GDPR*)

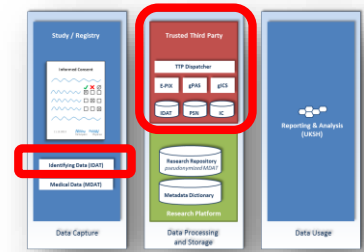


# Infrastructure



# Use Case 1: Register Patient for BFCC

## Register new participant (IDAT) via Trusted Third Party



The screenshot shows the 'New Participant' registration form in the BFCC-QA system. The form is titled 'New Participant - Acquisition of person-identifying data (IDAT)'. It includes a header with logos for Interreg Baltic Sea Region, the European Union, and BFCC. Below the header, there is a note: 'Mandatory fields are marked with \*'. The form contains the following fields:

- Last name \*
- First name \*
- Maiden Name \*
- Date of birth (DD.MM.YYYY) \*
- Place of birth \*
- Gender \* (Please select...)
- Address \*
- Place of residence \*
- Zip Code \*
- Telephone number
- e-mail address

At the bottom of the form, there are 'Cancel' and 'Next' buttons, and a 'Clear fields' link. The footer of the form reads: 'Independent Trusted Third Party of the University Medicine Greifswald. Version: 1.2.0-SNAPSHOT'. The background shows the BFCC-QA interface with a table for patient data and a sidebar with navigation icons.

# Use Case 2: Search existing Participant

Enter name, select result and access patient documentation using Trusted Third Party



Search Participant (Trusted Third Party)

Interreg Baltic Sea Region | EUROPEAN UNION | BFCC Baltic Fracture Competence Centre

*Search Participant*

o Please enter first name and/or last name to obtain first results.

Name:

1 result(s)

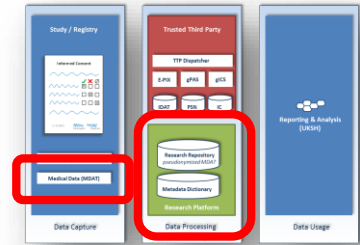
| Last name  | First name | Gender | Date of birth |
|------------|------------|--------|---------------|
| Mustermann | Max        | male   | 01.01.1990    |

Independent Trusted Third Party of the University Medicine Greifswald. Version: 1.2.0-SNAPSHOT

Search criteria sidebar:  [Extended search...](#) [Trusted Third Party patient search](#)  Use local search

# Use Case 3: Medical Data Entry

Fill in medical data in registry (here: participant fracture data)



**Fostering innovation for better fracture management**

Diagnosis

Diagnosis no. \*

AO-fracture classification: \*  ⓘ

[graphically assisted coding by AO Foundation](#)

Diagnosis according to ICD-10 classification:  ⓘ

Open fracture? \*

Bone density:

Bone density according to US Density Index in g/cm<sup>2</sup> (0 - 2.00):

Cortical thickness, proximal tibia in mm (0.50 - 10.00):

01 - normal

02 - low bone mass

03 - osteoporosis

04 - severe (established) osteoporosis

99994 - device not available (not measured)

99995 - not measured (device available)

99999 - not documented

CRF CentraXX ID: 259  
Study center: Lithuanian University of Health Sciences (LT\_LUHS)  
Created by: test\_litschkot last change by: approved by: verified by:  
Created on: 2018-10-17 11:58 last change on: approved on: verified on:  
Person responsible:  
Source system: CentraXX

# Fracture Registry Sites

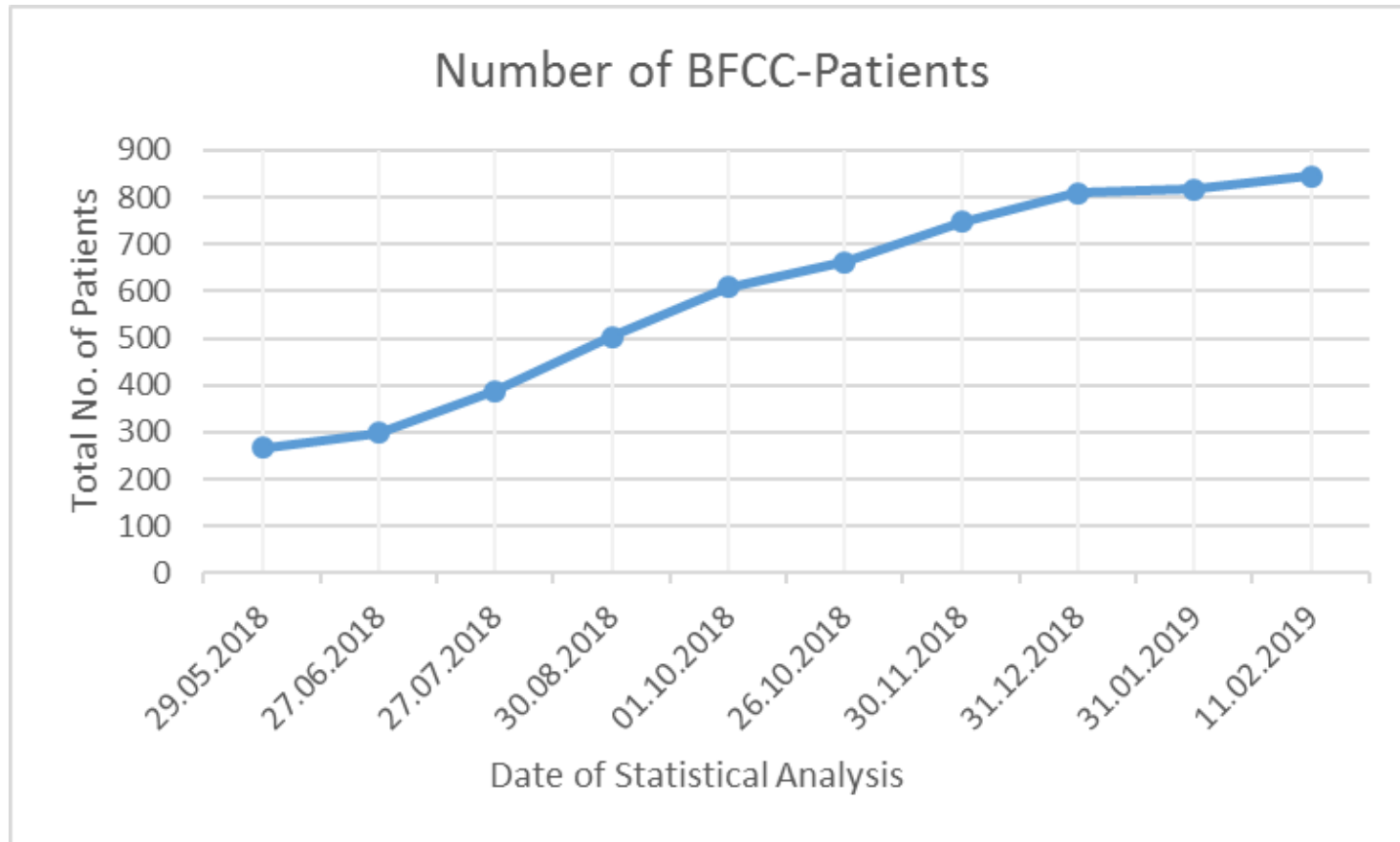


- Connection active (4)
- Connection on-going (1)
- Transnational Fracture Registry

Source: <https://www.bfcc-project.eu/registry.html>, accessed 2019-01-28

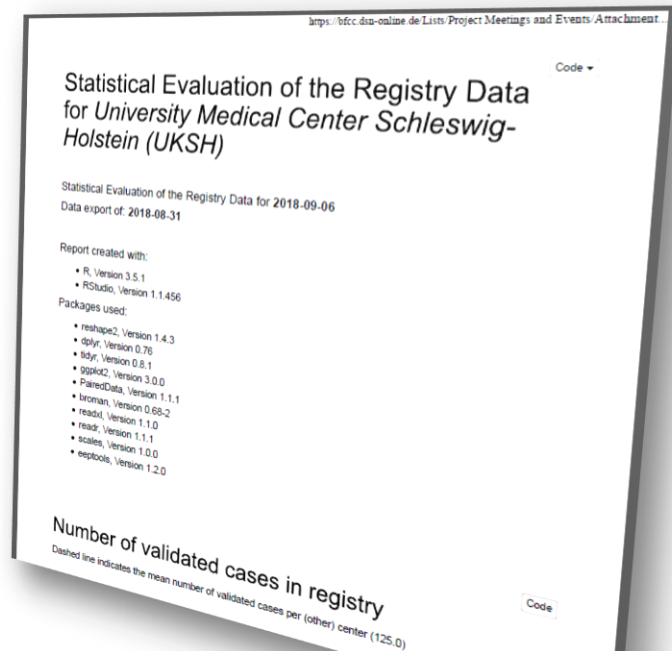
# Number of Patients until February 2019

- First patient-in was in December 2017.

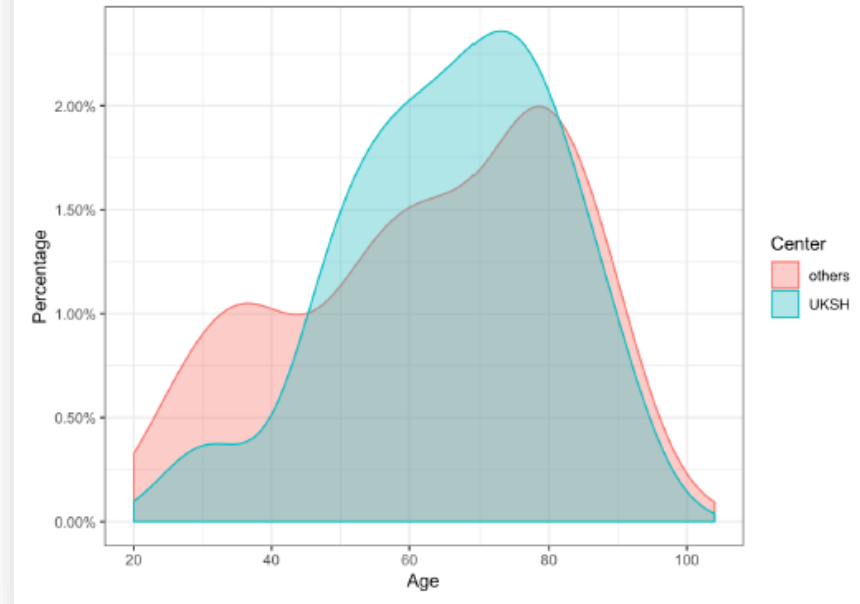


# First Results

- Data input on-going
- Challenging endeavour
- TFRP site-specific Reports by UKSH



Distribution of Age (at time of fracture)



Interested? See „How to get access to the BFCC?“  
at <https://www.bfcc-project.eu/registry.html>

If you want to join the project or have further questions, please contact



## Project Contact

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EUROPEAN UNION  
EUROPEAN  
REGIONAL  
DEVELOPMENT  
FUND



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**Thank you!**

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