

# Requirement Engineering Workshop – Germany

## Summary

<b>Date/Time</b>	27 <sup>th</sup> April 2017
<b>Venue</b>	Kieler Wissenschaftszentrum, Fraunhoferstraße 13, 24118 Kiel, Germany
<b>Host</b>	Life Science Nord Management GmbH
<b>Participants</b>	<p>Bernard Brandewiede, Amedon GmbH - <b>Industry</b></p> <p>Kai Dierks, Soventec GmbH - <b>Industry</b></p> <p>Sabine Fuchs, UKSH Kiel, Klinik für Orthopädie und Unfallchirurgie - <b>Clinic</b></p> <p>Fenja Gengelazky, DSN - Connecting Knowledge - <b>Others</b></p> <p>Oliver Hass, BSN medical - <b>Industry</b></p> <p>Michael Krawczak, CAU, Institut für Medizinische Informatik und Statistik &amp; TMF – Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V. - <b>Academia</b></p> <p>Christian Lutz, Bluewater Medical GmbH - <b>Industry</b></p> <p>Carsten Schultz CAU, Institut für Innovationsforschung - <b>Academia</b></p> <p>Andreas Seekamp, UKSH Kiel, Klinik für Orthopädie und Unfallchirurgie - <b>Clinic</b></p> <p>Marion Zenthoefner, Project manager Northopedics - <b>Others</b></p> <p>Anna-Winona Struck, Life Science Nord Management GmbH - <b>Organiser</b></p> <p>Julia Brillling, Life Science Nord Management GmbH - <b>Organiser</b></p> <p>Anna Eckers, Life Science Nord Management GmbH - <b>Organiser</b></p>
<b>Moderation</b>	Anna-Winona Struck, struck@lifesciencenord.de

We face the need to improve knowledge about fracture management due to an aging society. Therefore, the BFCC project aims to collect patient data within a transnational registry, from which different groups of stakeholders will benefit. Interests of the stakeholders include for example:

- Identification of clinical requirements in current treatment practices
- Performance of pharmaceuticals, devices and implants
- Adaption of guidelines

The goal of this first workshop in Germany was to identify needs from academia, clinics and industry to be able to adapt the registry according to the requirements. Moreover, the workshop participants had a closer look to the data set, which has been developed by the project partners.

### Agenda/Topics:

- Introduction to the BFCC - Overview of the project
- Overview of the Danish and Swedish registries - How do they look like?
- The Data Set of the BFCC - Including the common minimal data set
- The BFCC Knowledge Platform - Including interactive stakeholder mapping

## Key findings:

### Goal and results of the registry:

- Which questions the registry wants to answer should be well-defined. It is better to focus on a few key questions than trying to answer a large range of questions.
- The workshop participants agreed that it would be an advantage to include the success of surgery, treatment and post-treatment in to the registry (post-clinical processes) as follow-up analysis is currently not a standard in Germany. These results could be used to evaluate the current healing classification system and to develop a novel healing classification system.
- It would be interesting to include Patient-Reported Outcome Measures (PROMs) in the registry as they are becoming more and more important.
- The registry should provide information about the outcome of the treatment (cost and quality) to answer questions like: Which therapy is the cheapest and most effective? Whose fault is a non-successful treatment (implant, doctor, patient etc.)?
- A comparison of standards in different countries would be interesting.

### Data set content ([http://www.bfcc-project.eu/files/MinimalDataSet/bfcc\\_dd\\_browser.html](http://www.bfcc-project.eu/files/MinimalDataSet/bfcc_dd_browser.html)):

- It is very important that the minimal data set of the registry is not too long. It currently contains over 40 entries which is seen as too many from the workshop participants (suggestion: 15-20 entries). There is a risk that the quality of the filled-in data will decrease if the time to fill it in increases. Incentives to use the registry should be clarified. Furthermore, the minimal data set has to be tailored to the question that the registry aims to answer.
- It should be investigated if it is possible to integrate information from hospital information systems, health insurances etc. in to the registry to use as many already existing data as possible.

### Quality control, ownership and governance:

- The workshop participants recommended an international, external review board for the data set and the possibility to influence the data set by the medical societies of the participating countries (e.g. Osteosynthesis and Trauma Care Foundations).
- The long-term governance and the ownership of the registry data has to be clear. One possibility could be an international non-profit organisation.



Photo 1 by Fenja Gengelzky, DSN



Photo 2 by Fenja Gengelzky, DSN

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Photo 3 by Fenja Gengelazky, DSN