From research to clinics: An example of clinical translation of MR guided FUS treatment of the liver

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Vision

FUS in moving organs can be realized by updating the focal spot position to follow the target motion (steered FUS). However, up to today, there is no software support for this kind of treatment.

Without steering the energy is distributed to a larger volume. Steering leads to a sharp heating pattern.

Since we are developing such a treatment system which can deal with focused ultrasound in moving organs, quality assurance is an important aspect in the project.

Quality assurance in TRANS-FUSIMO

- Quality assured development of prototype and algorithms
- Validation of complete integrated system
- Animal and patient studies

TRANS-FUSIMO Treatment System

- Connection to MR device
- INSIGHTEC: FUS transducer API
- mediri: US and MR tracking algorithms
- ETH: Motion model to predict position of the liver
- Fraunhofer: Temperature monitoring

Research vs. use in clinical studies

Research
- Motion model algorithms
- Tracking algorithms
- Thermometry algorithms
- FUS simulation

System ready for use in clinical studies
- Aim is to perform animal and human trials (according to ethical guidelines)
- Perform clinical trial according to 93/42/EWG Annex X
- Ensure quality standards by developing and validating according to 93/42/EWG and IEC 62304 in compliance with ISO 13485

Relevant norms and directives

- European medical device directive: 93/42/EWG
- Both development and validation have to be performed according to ISO 13485 (quality management system for medical devices)
- Risk management according to ISO 14971
- Included software has to comply to IEC 62304

Results

If a clinical investigation shall be performed using non CE marked systems, the developers have to ensure a CE mark ready status of the quality management.

In TRANS-FUSIMO, the parties responsible for the development of the treatment software as well as its preclinical validation have ISO 13485 accreditation which enables the use of the developed tools also in clinical investigations after successful pre-clinical validation followed by a effective and efficient animal trial.

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