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

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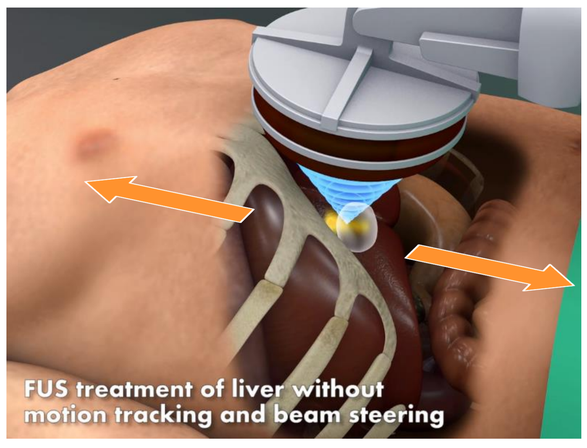
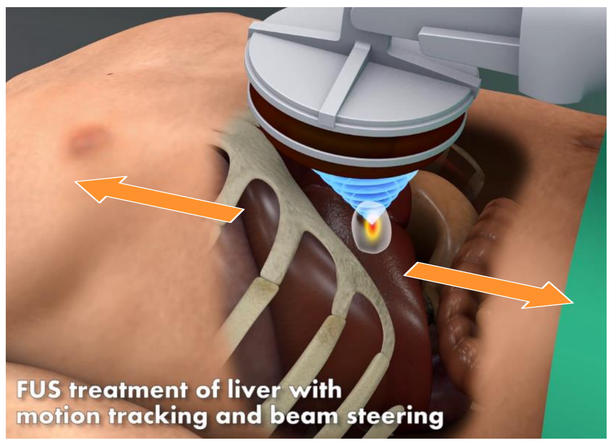
Vision

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.



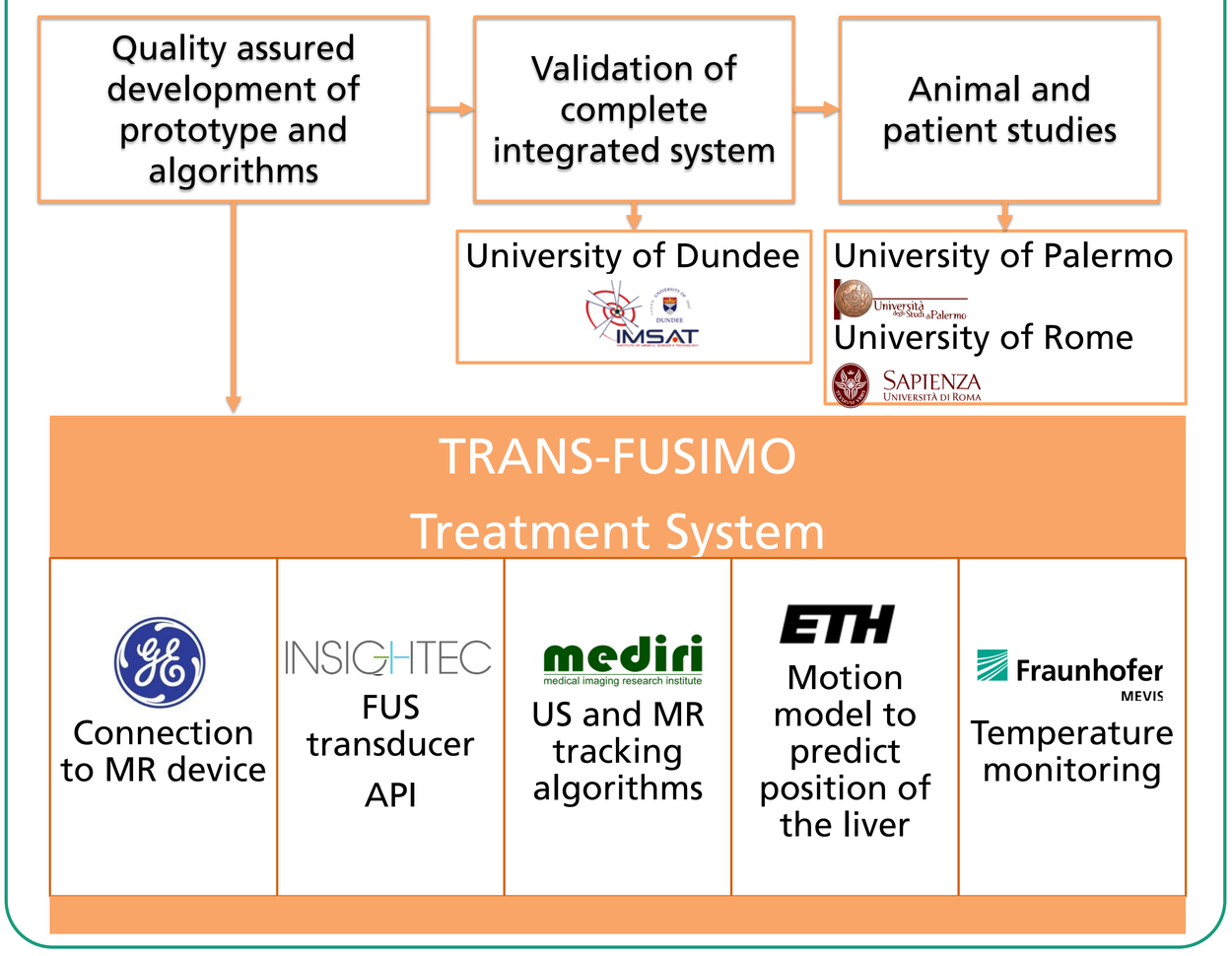
Without steering the energy is distributed to a larger volume.



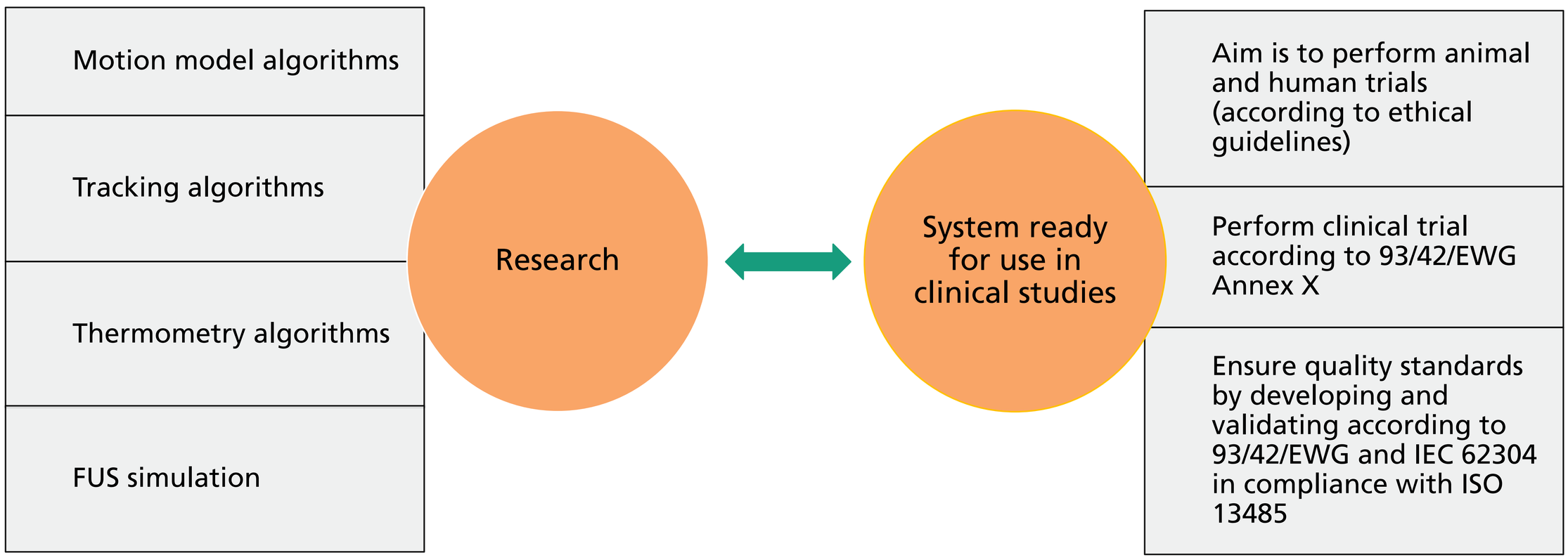
Steering leads to a sharp heating pattern.

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

Quality assurance in TRANS-FUSIMO



Research vs. use in clinical studies



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

Acknowledgements

The research leading to these results has received funding from the European Community's Seventh Framework Programme FP7/2007-2013 under grant agreement n°611889.

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.