EMPIR Call 2020 – Fundamental, Industry and Normative

Selected Research Topic number: **SRT-n13**
Version: 1.0

Title: Improved metrology for quantitative MRI

Abstract

The lack of standardisation in quantitative MRI (qMRI) use is limiting the introduction of Artificial Intelligence (AI) for patient image analysis and the combination of multi-centre data generated in clinical trials to identify successful therapies. The closest applicable international standard is IEC 60601-2-33 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. However, this does not have the necessary measures to enable standardisation nor to introduce qMRI image comparability. The introduction of reference materials and best practice for their use, underpinned by normative standards would introduce the first steps towards greater qMRI comparability between clinical centres.

Keywords

harmonisation of MRI images, qMRI calibration, standardisation, uncertainty, traceable test objects, standardised procedures, best practice, scanners, T1, T2, fat fraction, dimensional metrology,

Background to the Metrological Challenges

Quantitative MRI can be used to detect and monitor the four most prevalent fatal diseases in OECD countries - Cancer, Heart disease, Dementia, and Stroke. Thousands of MRI scanners from different manufacturers, with various ages, field strengths and pulse sequence implementations are maintained by European national health services. Images produced at different sites using different scanners are not comparable leading to problems in determining effective treatment thresholds or identifying successful therapies during clinical trials. Whilst quantitative imaging has the potential to identify novel biomarkers and for use in clinical diagnosis and prognosis, standardised use guidelines are needed to enable harmonisation of image analysis between clinical centres.

Improved traceability for qMRI scanners and greater image comparability could be achieved by introducing measurements of well characterised reference materials suitable for assessing a scanners response to contrast agents with an emphasis on removing dependence on physical quantitative measurements. Areas where this would generate patient benefits include the T1 and T2 mapping used to diagnose heart failure, Apparent Diffusion Coefficient (ADC) mapping used for ischemic stroke diagnosis, and maps indicating the response of cancerous tumours to therapy.

To promote the use of the developed reference materials and the image harmonisation that this would generate to the qMRI community, a multi-centre trial is recommended to engage with clinical users and provide a feedback route for the best practice procedures proposed. Interactions and consultation with the ISO and CEN/CENELEC committees responsible for standardisation in this area should be anticipated to facilitate the dissemination and incorporation of the developed best practice into normative standards.

Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on the development of traceable measurements and characterisation necessary to support standardisation in quantitative MRI (qMRI).

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The specific objectives are:

1. To develop traceable novel material measurement and manufacturing methods (with a focus on contrast agents), for use in the quantitative assessment of qMRI on individual scanners. In addition, to develop robust methods for data analysis and uncertainty quantification for qMRI measurands, and to apply these methods to specific qMRI image measurements such as T1, T2, fat fraction, diffusion measurement and dimensional metrology for features.
2. To demonstrate the efficacy of the traceable methods, which were developed in objective 1, in a large-scale multi-site study.
3. To publish methods and best practice guides based on the results from objective 2. In addition, to develop guidelines on the harmonisation of MRI images from large scale multi-site studies. The guidelines should be suitable for dissemination to standards developing organisations and to organisers of clinical trials.
4. To collaborate with the technical committees ISO/TC69/SC6/WG7 and CENELEC TC62, and the users of the standards they develop to ensure that the outputs of the project are aligned with their needs, including the provision of a report on qMRI calibration and the deployment of the test artefacts that are important for comparing MRI images, and recommendations for the incorporation of this information into future standards at the earliest opportunity.

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Regulatory body or Standards Developing Organisation or by a letter signed by the convenor of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects. The proposal must name a “Chief Stakeholder”, not a member of the consortium, but a representative of the user community that will benefit from the proposed work. The “Chief Stakeholder” should write a letter of support explaining how their organisation will make use of the outcomes from the research, be consulted regularly by the consortium during the project to ensure that the planned outcomes are still relevant, and be prepared to report to EURAMET on the benefits they have gained from the project.

Proposers should establish the current state of the art, and explain how their proposed research goes beyond this. In particular, proposers should outline the achievements of the EMPIR project 18HLT05 QUIERO and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 0.8 M€, and has defined an upper limit of 1.0 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 30 % of the total EU Contribution across all selected projects in this TP.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded partners.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Transfer knowledge to the healthcare sector.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased

- organisations other than NMIs and DIs to be involved in the work.

Time-scale

The project should be of up to 3 years duration.