

## **Title: Metrology for additively manufactured medical implants**

### **Abstract**

Additively manufacturing (AM) medical devices and implants enables full part customisation. However, the technology has advanced at a much faster pace than regulations and quality controls. Non-destructive techniques and measurement protocols are needed for the traceable microstructural characterisation of internal features and defects in metal, polymer and ceramic AM implants. This will enable medical device manufacturers to fabricate more reliable products and will provide a validated way to non-destructively assess their quality. This work will go beyond state of the art by providing input to pre-normative standards for geometrical and dimensional tolerances of AM parts and in the long term will increase clinical acceptance of AM implants.

### **Keywords**

Medical devices, additive manufacturing (AM), patient specific implants (PSI), micro- and macro-porosities, bioinert metal alloys and ceramics, mechanical testing, computer tomography, surface scanning, patient specific guides (PSG), anatomical models

### **Background to the Metrological Challenges**

Additive Manufacturing (AM) is the process that allows complex parts, such as patient specific implants (PSI) and patient specific guides (PSG), to be manufactured specifically for the patient using 3D CAD models which are created using the patient's CT or MRI scans. PSIs can reduce removal of healthy bone, eliminate the need for bone grafting, promote effective planning of implantation/surgery and shorten the time of anaesthesia. PSGs are tools that enable accurate cutting of the patient's bone which facilitates accurate placement of bone grafts and implant placement on the patient. The potential benefits of AM in the medical sector for patients and overall medical costs are very large, because of reduced operating time as well as less intrusive and personalised surgery. A number of European companies use AM based technologies, however currently internal company policies are used during the manufacturing process and these strongly vary among manufacturers. Current design and manufacturing process, contains a number of steps, from the formation of the initial CAD model through to the final manufacture, each of which can introduce dimensional errors in the order of 100  $\mu\text{m}$  to 200  $\mu\text{m}$ . The scientific literature shows a dimensional accuracy variation from 3 % to 0.2 % with typically measurements being carried out only once, and the repeatability of measurements is not reported. The material used also has an influence on the dimensions of parts; with ceramics and metals behaving differently during manufacture. Traceable measurements and standards are needed in order to quantify and detect all the dimensional errors in the production chain of AM products (including internal and external features). In addition, the surface characteristics and pore size and orientation in lattice structures of implants are critical parameters for patient outcomes. The surface roughness is paramount to material resorption and hence the longevity of the implant *in-vivo* and still needs to be appropriately quantified. While this is mostly a clinical problem, proper metrology studies in this field are still missing. Based on the literature, there is no consensus on the ideal pore size or pore orientation in lattice structures. It is therefore important to investigate non-destructive characterisation techniques to measure these parameters to be able to establish production chain standards for the AM-based technologies to assist in mechanical characteristics, biocompatibility and clinical evaluation.

### **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 traceable measurement and characterisation of additively manufactured materials and technologies.

The specific objectives are;

1. To optimise and validate non-destructive characterisation techniques, and to develop traceable measurement capabilities for the determination of micro-structural parameters and meso-structural parameters and patient-specific guides (PSG).
2. To develop and validate AM lattice structures and demonstration materials for bone replacement, from initial computer assisted design (CAD) through to final manufacture to quantify pre-clinical fit (which needs to be of the order of 100  $\mu\text{m}$ ) of implants to the original bone surface on which they were designed.
3. To quantify dimensional measurement errors, in the order of 100  $\mu\text{m}$  to 200  $\mu\text{m}$ , in the whole process of personalised body part replication.
4. To assess and quantify the effect of dimensional errors on implant efficiency.
5. To facilitate the take up of the technology and measurement infrastructure developed by the project by the measurement supply chain (accredited laboratories, instrumentation manufacturers), standards developing organisations (ISO/TC261, CEN/TC438, ISO/TC119, etc.) and end users (implant manufacturers and clinicians).

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes, and it is expected that multidisciplinary teams will be required. To enhance the impact of the research, the involvement of the appropriate user community such as medical practitioners, medical (academic) hospitals and industry is strongly recommended, both prior to and during methodology development.

Proposers should establish the current state of the art, and explain how their proposed project goes beyond this.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.8 M€, and has defined an upper limit of 2.1 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 35 % of the total EU Contribution to the project. Any deviation from this must be justified.

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 medical device 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.