



## **ESR statement on the European Commission Staff Working Document on the use of '-omics' technologies in the development of personalised medicine (SWD 2013/436)**

The European Society of Radiology (ESR) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the professional and scientific activities of radiology in all European countries. The Society's mission at all times is to serve the healthcare needs of the general public through the quality of service and the support of education and research in the field of radiology. The ESR is the European body representing the radiology profession with more than 58,000 individual members and acts as the umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology.

The ESR is convinced that personalised medicine can provide enormous benefits for patients and healthcare practitioners and that it has the potential to shape the delivery of healthcare services in Europe in the future, as developments in medical research and technology have enabled us to develop -omics technologies for profiling patients to individualise treatment. Given the scale of this approach, and the number and diversity of stakeholders involved, it is altogether proper and necessary that the European Union actively address this issue and ensure an adequate, conducive framework that encompasses every aspect from fundamental research to post-treatment follow-up with patients.

However, the ESR, as the organised representation of radiological disciplines in Europe, is of the opinion that, from a scientific and medical perspective, it is absolutely essential that medical imaging be recognised alongside -omics technologies as an integral part in the development of personalised medicine. Imaging's contributions – detection and staging of disease, guiding tissue sampling for molecular profiling, imaging biomarkers in patient profiling for preventive and predictive medicine, assessment and prediction of response to treatment – are vital necessities for the very concept of personalised medicine.

While the ESR welcomes the fact that the European Commission is seriously addressing the issue of personalised medicine, and that the staff working document rightfully stresses the important role of -omics technologies, it must be pointed out that the sporadic attention given to imaging is not justifiable on scientific and medical grounds. Personalised medicine simply cannot be developed successfully without utilising medical imaging to the fullest extent.

In the following, the ESR therefore proposes a list of key items that it deems imperative to be included in the staff working document from an imaging perspective.

### **Recognition of the Role of Imaging**

It is particularly important for the ESR that the essential role of imaging for personalised medicine be explicitly acknowledged. Imaging should be considered on a par with -omics technologies because imaging biomarkers are essential for linking determinants of disease to health outcomes, thereby enabling the targeted prediction and prevention of diseases, and the prediction of treatment response. For this reason, the ESR proposes that the role of imaging should be acknowledged alongside the references to -omics technologies in the Introduction of the SWD.

### **Imaging Biobanks**

The development of imaging biobanks, and their integration with existing -omics biobanks, is vitally important for personalised medicine. Imaging has very specific requirements regarding the storage, codification, standardisation and interoperability of the data generated. This poses unique challenges from a technical standpoint, due to the type and amount of data to be handled. These aspects pertaining to imaging should be reflected in the chapters on biobanks and harmonisation of data (3.1.4), biomarker identification (3.2.1) and technical aspects and challenges (3.2.2).

### **Imaging Biomarkers**

In chapter 3.3.1 on biomarker qualification and validation, the need for standardisation and validation of imaging biomarkers should be included, as these are important aspects for their development in a technically valid, robust and reproducible way. Qualification of imaging biomarkers is also relevant for their inclusion in drug development.

### **Regulatory Framework and Clinical Trials**

The chapter on the regulatory framework (4.2) should make specific reference to several issues pertaining to imaging biomarkers specifically. The ESR considers it important that imaging biomarkers be incorporated in clinical trials as well as drug and device approval processes; however, at this stage, the regulatory processes for qualifying imaging biomarkers are very complex, and need to be improved.

Clinical trials (4.2.2.2) are an area where imaging biomarkers can play a key role, particularly in the development of new drugs, where they could be used to select patients for clinical trials or to evaluate the effect of drugs (surrogate endpoints). In order to achieve reliable and high quality outcomes, imaging biomarkers need to be clinically validated, which could be facilitated through their increased use in clinical trials and during drug assessment studies. The ESR urges the European Commission to support its call for including imaging biomarkers in clinical trials and drug approval processes whenever possible. This should be reflected in the staff working document.

### **Radiogenomics**

The SWD does not mention the promising field of radiogenomics, which the ESR considers to have enormous potential for the development of personalised medicine. It should therefore be an indispensable part of any document on this subject. As a rapidly growing discipline

that correlates radiological information with genomic data, it links imaging with -omics technologies and is therefore a particularly relevant field for personalised medicine. The ESR considers it very important that research in the field of radiogenomics is strengthened, which is why it is deemed necessary that the European Commission recognise this in the report and take it into consideration in the development of research agendas and regulatory frameworks.

In addition to this statement, the ESR would also like to refer to the following documents:

European Society of Radiology (2011). Medical imaging in personalised medicine: a white paper of the research committee of the European Society of Radiology (ESR). In: *Insights into Imaging* (2011) 2:261-630. Available [here](#).

ESR Press Release (2013): *Imaging key factor in personalised medicine: individualising healthcare requires combined effort*. Available [here](#).

ESR Report (2013): *'The Role of Radiology/Imaging in Personalised Medicine: How to provide the right prevention and treatment to the right patient at the right time? A Roundtable Event hosted by Dr. Biljana Borzan MEP at the European Parliament Brussels'*. Available [here](#).

The Parliament Magazine (2013). *Meeting the Challenge - A Parliament Magazine Special Supplement on Personalised Medicine* (September 2013). Available [here](#).