

IMI consultation on advanced therapies

Response from the European Society for Molecular Imaging (ESMI)

I am responding to your ATMP Concept Paper with your call for input to this Concept Paper.

My response is on behalf of the European Society for Molecular Imaging (ESMI), whose President I am.

For your background, let me start with a short paragraph describing ESMI and its functions.

The European Society for Molecular Imaging (ESMI) is an independent, non-profit, scientific society of public interest founded in 2005. The ESMI represents an academic community of imaging scientists (physicians, engineers, chemists, physicists, biologists, computer scientists,...) all across Europe and beyond and is providing an interdisciplinary platform for knowledge exchange. The ESMI is committed to scientific and technical excellence covering basic sciences, translational aspects as well as clinical applications.

To date the ESMI has 956 individual members. The number of members has been continuously growing over the past decade.

Besides the day-to-day activities of a scientific society like the coordination of study groups, Board issues and elections, supervising the ongoing research and funding activities, (...) the ESMI is organizing three main scientific events per year:

- 1) its annual meeting the European Molecular Imaging Meeting - EMIM with about 600 participants
- 2) a more biology-focussed winter school TOPIM (hot topics in imaging)
- 3) the newly established imaging technology summer workshop TOPIM TECH (Hot Topics in Imaging Technology). Further information can be found at www.e-smi.eu and via office@e-smi.eu.

Taken all these activities together, ESMI acts as the major voice representing the Molecular Imaging Community and its expertise in this field in Europe.

Concerning the ATMP Concept Paper:

We consider this Concept Paper a timely and coherent analysis of the situation of ATMP in Europe. We would, however, like to add that the role of molecular imaging must be emphasized more both in the preclinical as well as clinical development. Assessment of a particular approach in relation to its treatment efficacy, safety, and monitoring of organ/body response will be improved substantially through protocol integrated application of standardized imaging protocols. Noninvasive imaging procedures such as MRI, PET, (intra-operative) fluorescence imaging provide a triple level of information on the individual:

- 1) The disease / lesion is monitored in its pathophysiological development
- 2) The treatment is followed directly (e.g. for cell fate imaging in cell therapies), providing information on therapeutic efficacy
- 3) The response of the organ / whole body to the treatment is monitored for safety and outcome

Future personalized medicine strategies will highly depend on this triplicate level information provided by noninvasive Molecular Imaging. Moreover, this complex information provided by one technological approach, namely molecular imaging, will increase the efficiency of ATMP evaluations thus substantially helping to reduce development costs.

We therefore emphasize the advantage of implementing imaging based protocols as quality assessment for the development of ATMPs, both on the preclinical and clinical level.

For further discussion on this focus, representatives of ESMI will be happy to respond.

Respectfully yours,

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President, ESMI

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