

IMI consultation on advanced therapies

Response from Gabriele Thumann

Dear Sirs and Madams,

I gladly read the concept paper “Innovative Medicines Initiative consultation – Facilitating the translation of advance therapies to patients in Europe”.

As coordinator of the EU funded project TargetAMD with the ultimate goal of exactly that – the translation of an ATMP to a clinical trial, I am interested in your initiative and will support your effort as much as I can.

Your concept paper greatly unifies main issues and key challenges we have to consider, but let me answer your questions detailed:

1. Have the key challenges that can be addressed through collaborative, public private initiatives been properly identified?

Yes.

2. Which of the proposed potential initiatives should be prioritised?

In the TargetAMD project we made the experience that the manufacturing of the ATMP or, in our case, the GTMP, respectively, constitutes the major challenge in the project. The key issues were i) where can I produce a GMP-grade GTMP (not every hospital has a clean room), ii) the organisation and provision of sufficient personnel (the personnel effort is extremely high) and iii) the development of appropriate release controls, acceptable for the quality assurance of the clean-room facility and for the regulatory authority, Swissmedic (for such new approaches no guidelines or recommendations exist).

3. Are any areas missing?

You mentioned the release controls for viral systems, but also new release controls for non-viral technologies and special surgical procedures need to be developed. In TargetAMD, e.g., we will harvest, transfect and transplant a small autologous patient biopsy in 1 surgical session of approximately 60 min. The low number of cells and the tight schedule issued a special challenge to us.

4. What are the key European or national initiative that IMI shall synergies with?

The development of new techniques and methods for the quality analysis for release controls during GMP-grade manufacturing should be promoted and harmonised in Europe.

Best regards

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