

Transfer of research results into the market: How to optimise a safe, fast and economic process to implement personalised medicine approaches?

Working Group III



Panel:

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Leading questions:

- Technological challenges for Personalised Medicine research. Data generation and analysis.
- Methodological standards for Personalised Medicine studies.
- Which issues related to market and regulation have to be addressed first in order to facilitate market access of Personalised Medicine approaches?
- Entrepreneurial challenges common to all the previous questions.

Wrap up discussion points

- What is specific for PM vs. generic issues in the development of health products and IVD ?
 - Diagnostic / stratification ? Ex. new taxonomy
 - Treatments ? Ex. tissue-agnostic indication
- What should be the funding mechanisms / instruments for the various steps in PM development programmes ? (stratification, translational, clinical step)
- Beyond market access, what is the evidence required to foster adoption by HTA / insurance ?
- Industry missing in the discussion

Needs to address bottlenecks

- Need for early support to design the development plan
 - technology transfer
 - regulatory experts
 - ‘scientific advice’
 - HTA / payers
- Need for training and for new competencies (IP, data science, regulatory)
- Need for economic expertise, how will PM contain the cost of healthcare ?

Optimise the transfer of research results to market ?

- Training, support and expert advice
- Involment of HTA and health insurance
- Need to identify what are the industry expectations
- Need for venture capital investment