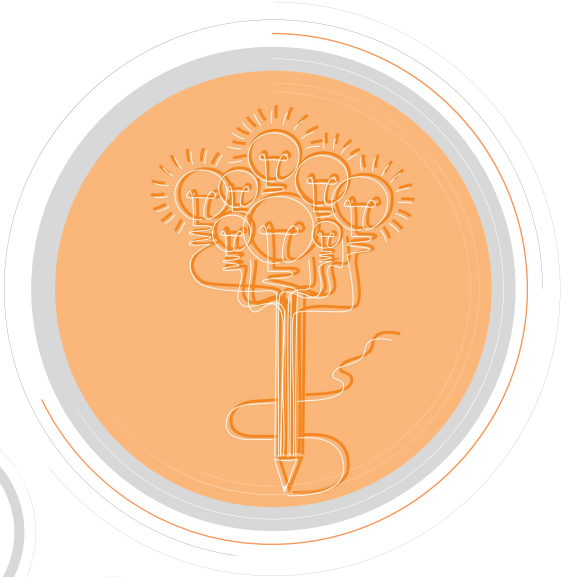
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Support developments in precision medicine, biomarkers and 'omics'



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Martina Schussler-Lenz, CAT on 18 November 2019
Presented by Ana Hidalgo-Simon, Head of Specialised Scientific Disciplines Department, EMA

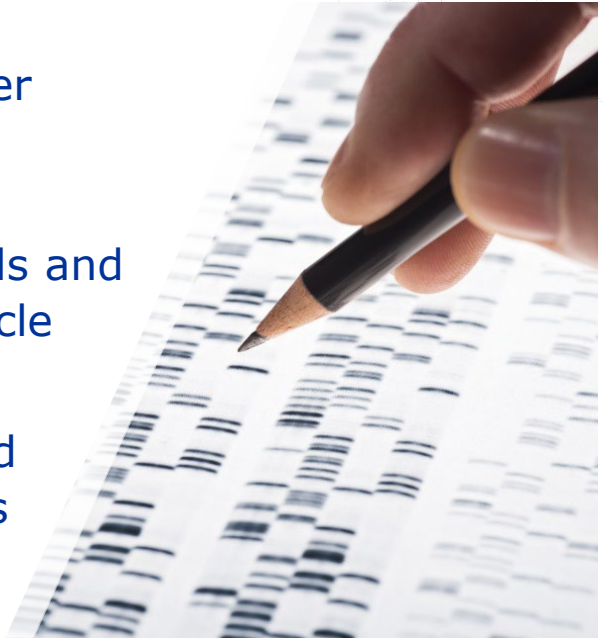
Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

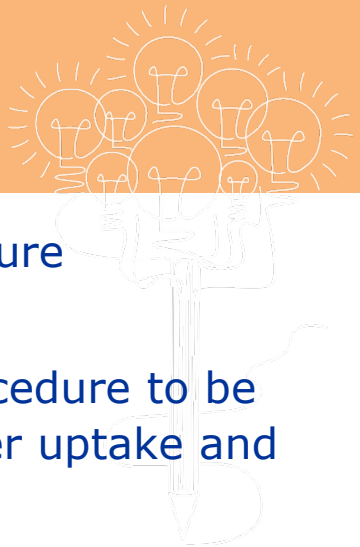
The fact that these comments from stakeholders are displayed in the presentation does not mean we endorse them or commit to fulfil them in any way.

Support developments in precision medicine, biomarkers and 'omics'

- Enhance early engagement with novel biomarker developers to facilitate regulatory qualification
- Address the impact of emerging 'omics' methods and their application across the development life cycle
- Evaluate, in collaboration with HTAs, payers and patients, biomarker impact on clinical outcomes

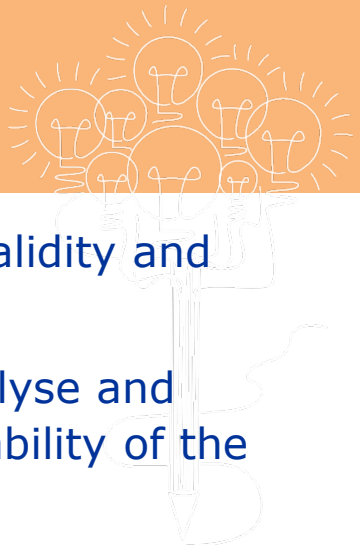


Enhance early engagement with novel biomarker developers to facilitate regulatory qualification



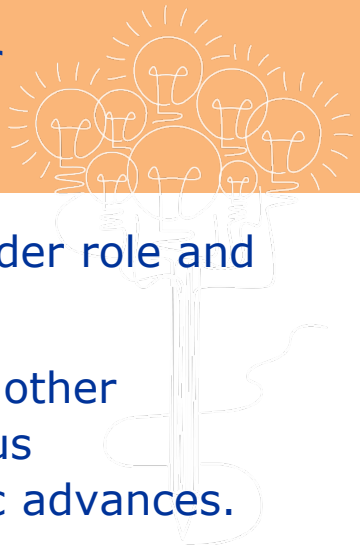
- EMA/EC should develop a consistent diagnostic testing infrastructure throughout Europe.
- Enhance the current EMA qualification procedure to allow the procedure to be accelerated and provide for greater flexibility to encourage greater uptake and use.
- Develop guidance on the use of next generation sequencing in an investigational setting, including performance evaluation, requirements for concordance/sensitivity testing, and for complementary diagnostics.

Address the impact of emerging 'omics' methods and their application across the development life cycle



- Develop research projects to ensure the quality, completeness, validity and analysis of datasets.
- Develop informatics, ICT and mathematics tools to integrate, analyse and extract value from databases with specific attention on interoperability of the respective databases.
- EMA and EC to develop a coherent plan that fits into existing health strategic plans.

Evaluate, in collaboration with HTAs, payers and patients, biomarker impact on clinical outcomes



- In the enhancement of EMA biomarker qualification process consider role and use of data by HTA bodies.
- Support use of comprehensive genomic profile for diagnostic and other purposes, with fit-for-purpose performance metrics and continuous improvements mechanisms inbuilt to quickly incorporate scientific advances.
- Increase transparency: how biomarker and assay performance information are to be provided in the SmPC and companion diagnostics (CDx) label.

Any questions?

Further information

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