Report from the FEAM Forum Experts Round Table Discussion

27 September 2018

Geneva

Companion diagnostics and precision medicine: regulatory and uptake barriers to patient access

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Companion Diagnostics

"The success of personalized medicine depends on having accurate diagnostic tests that identify patients who can benefit from targeted therapies."

Dr. Peggy Hamburg and Dr. Francis Collins
"The Path to Personalized Medicine" New England Journal of Medicine; July 22, 2010

- Having a good test is as important as having a good drug

„It's all about finding the right patient
for a specific treatment"

Format and Objectives of the FEAM Forum of 27 September 2018

- The round table involved **representatives from different sectors in the biomedical community** (academia, industry, research organisations, healthcare professionals, etc.)

- **Objective:**
  - **Share information on existing initiatives** aimed at improving the links between CDx and precision medicine.
  - **Make suggestions for implementation** of CDx in daily practice
  - **Discuss current regulatory and implementation barriers**

Companion diagnostics and precision medicine: regulatory and uptake barriers to patient access

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Improving links between CDx and medicines - Regulatory barriers and possible solutions. Impulse presentations:
CDx in oncology Dr. Paul S Jones, Principal Translational Scientist, Cancer Research UK Centre for Drug Development
CDx in other therapeutic areas Dr. Thorsten Gutjahr, VP, Global Head of Companion Diagnostics, AstraZeneca
Current regulatory framework and ongoing EMA initiatives Dr. Marisa Papaluca, Senior Scientific Advisor & Dr. Falk Ehmann, Science and Innovation Support, European Medicines Agency (EMA)

Physicians' perspective Dr. Daniel Widmer, Vice-President, European Union of General Practitioners/Family Physicians (UEMO)
Genetic laboratories' perspective Prof. Vincent Mooser, CHUV - Lausanne University Hospital
Patients' perspective Dr. Stanimir Hasardzhiev, General Secretary, Patient Access Partnership and Board Member, European Patients' Forum

Main conclusions (1/3)

- CDx are critical tools for the implementation of precision medicine
- However, there are many challenges (including regulatory) related to their implementation in daily practice.

Challenges:

- Identification of resistance biomarkers to targeted therapies/immunotherapy in oncology
- Identification of biomarkers of efficacy of immunotherapy
- Democratization of high throughput technologies to identify targets
- Understand patients and physicians needs
- Availability of suitable sample
- Genetic association ≠ clinical utility
- Strong evidence sufficient to modify medical practice available only for a minority of drug – gene couples

Main conclusions (2/3)

The role of physicians/GPs:

- Important to recognise the role of GPs as « mediators »
- Explanations take time on patient-physician relationship
- Specific training for explanations and anxiety management (the predictive aspect brings indeed a risk of increase anxiety)

Main conclusions (3/3)

Patients' access:

- Precision medicine is a patient-centred approach and goes hand in hand with CDx
- Therefore, all patients need to access them (no matter where they live)
- However, access to CDx is still problematic (especially in Eastern Europe countries): reimbursement and awareness/training of clinicians is an issue
- Academia, healthcare professionals, industry and patients should work together to convince payers and governments that CDx can be cost-effective

Patients Perspective – General Conclusion

Stanimir Hasardzhiev, MD

- In order to enable access and reduce inequalities for all patients:

We should make sure that patients are involved in the entire lifecycle of PM and CDx.

We should stop paying for PM and CDx as we are used to. We should price and pay for what we gain from them as a society and individuals.

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Thank you!

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