CDDF Workshop

Biomarkers and Patient Access to Personalised Oncology Drugs in Europe

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Is a completely tailored approach to treat cancer achievable?

Highlights of the Discussion

Benefits are clearly articulated by all stakeholders

- Smaller sample size required in trials
- Saving resources and improving cost-effectiveness
- More confidence in patient outcomes

Importance of Companion Diagnostic tests (CDx)

- Lowering medicines development costs
- Avoiding delays to treatment time
- Increasing efficacy of treatments
- Lower cost of CDx compared to Rx

Challenges are many for Biomarkers esp. in Europe

- Numbers of patients available for trial testing is shrinking
- No clarity regarding expectations from the regulators, no suitable path for regulatory approval and reimbursement
- Costs driven by multiple tests result in emergence of homebrew tests

Meeting Outcomes

- *The one test – one medicine paradigm is not to last*
- *The biomarkers development path is split into two approaches*
  - *Hyper individualized therapy based on biomolecular phenotypes*
  - *Biomarkers defined subgroup analysis leading to stratified medicine*
- *Challenges arise for all biomarkers types*
  - *Single analytes compete more with home brew tests*
  - *Multianalytes present more reimbursement challenges*
  - *Multianalyte assay with algorithmic analysis a good avenue- challenges in implementation and reimbursement*
- *Use of historical controls are part of the solution to demonstrate Biomarkers utility -*
  - *Address the recruitment challenge, HTA questions at once*
- *Despite some successes, there is a need to align the stakeholders on the importance of bringing biomarkers to the European Market*
  - *This slow pace for biomarkers slows down the development of stratified medicine*

This is where industry and academia have been successful so far

Information is difficult to find for patients
Patients feel biomarkers increase their time to access treatment
Self pay tests are no solution as their accuracy and utility is poorly documented

Take-Home Messages & Next Steps

There is no silver bullet, progress will involve:

- Innovative and validated methodologies to design trials
- A pro-active approach to harmonise HTA processes (from Eunethta) could be part of the solution
- Innovative access strategies to support timely patient access, while need from payers and providers to assess value is important
- A specific data privacy framework to keep, protect and share patient data for research purposes and identify suitable biomarkers
- Leadership or ownership of the theme to support concerted stakeholders approach