

BIOBANKING AND MOLECULAR PATHOBIOLOGY WG

OECI EUROPEAN MISSION WORKING PARTY: B&MP VIEW

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CANCER AT MOLECULAR LEVEL

<u>STATEMENT 1</u> :

"Cancer is a disease defined by spatial and temporal variables:

-topological heterogeneity -change of the genetic-molecular make up during its evolution.

These two features represent the major hurdles toward an effective cancer therapy"

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 - with short responses (resistence prevails on sensitivity)
 - still with too few predictive markers"

STATEMENT 2 " Precision medicine is a tool and like a tool it needs to be used appropriately and is NOT suggesting a HIGH RATE OF THERAPEUTIC SUCCESS"

PERSPECTIVES

<u>PERSPECTIVE 1</u> : "We need to acquire all the possible informations of every single patient and of his/her tumors (genetic-molecular, clinical, life style,environmental etc.).

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<u>PERSPECTIVE 2</u>: "To develop therapeutic approaches capable to overcome cancer heterogeneity and molecular dynamic evolution, we need more clinical driven FUNDAMENTAL RESEARCH to develop, in turn, new designs for genomic/molecular driven CLINICAL STUDIES".

European Commission Initiative on Breast Cancer (ECIBC) (Quality Assurance Development Scheme Group)



"Translation of genomics research into prevention, diagnostics and therapeutics of breast cancer" "Integrating genomics into personalised healthcare: a sciencefor-policy perspective "

2019 in Brussels



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Considerations:

With the increasing molecular information at DNA and expression level the value of classifications in oncology is decreasing and many tumours appear as a rare entity and the value of randomization in phase three trials is reduced.

The major problem is the low level of reproducibility in biological research with the necessity of standardization to allow exchangeability of the analysis results.

Consequences:

Necessity of clinical research performed directly in today patients (ECIBC).

Necessity of new types of clinical studies (N-1trials, Basket, Umbrella and Platform studies).

The solutions are coming from pre-analytical preservation of biological material (CEN and ISO technical specification), from standardization of molecular methods (guidelines, SOPs, external and internal quality controls, new IVDR) and intra-tumour heterogeneity specific sampling.

At institution level there is the necessity of accreditation and certification.

At European level there is the necessity of the preparation of new professionals.

OECI EUROPEAN MISSION WORKING PARTY: B&MP VIEW OECI Actions:

OECI Network may represent the second level for diagnostics and treatment in Europe.

There is the opportunity to improve accreditation especially at molecular pathology level (B&MP WG is involved already in pre-analytics, standardization and heterogeneity) to prepare CCC for a reproducible and exchangeble diagnostics and clinical research.

In OECI it is already started the discussion of new clinical studies (N-1 Approach) involving: -bioinformatics connections, -tumour boards,

-extensive data collection for rapid application of efficient new protocols.

A new European Molecular Pathology Master is in development for oncologists, pathologists and molecular biologists. OECI should take advantage of this to prepare a common terminology and standardization among the institutions.



GL Klement et al, Future paradigms for precision oncology, Oncotarget, 2016