Integrating Biomarkers into cancer clinical trials

Lawler, Schneider, Tejbar, Others

European Alliance for Personalised Medicine

Challenges

- Need for **rapid adoption** of validated cancer biomarkers into clinical practice
- **Much promise** following discovery research
- **Much less delivery** in clinical setting
- A number of barriers
  - Technical
  - Regulatory
  - Commercial
  - Reimbursement

- Clinical **Utility/Actionability**
- Best case **exemplars**
- **Real Life** data
- **Technical** considerations
  - Appropriate Standards
  - Disease stratification
  - NGS

Opportunities

- Common **Europe-wide platform** for biomarker discovery/development
- **Accelerate** application of biomarkers in clinical practice
- Need for **flexible Regulatory Framework**

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- Defining **evidence standards** for **clinical utility** and cancer **“actionability”** will provide an adaptable framework for **embedding biomarker** driven clinical studies into the cancer care pathway.

Implementing the results of innovative cancer clinical trials: addressing the cost versus value dilemma

Lawler, Sullivan, Others

- **Key foundation** for significant advances in oncology
- **BUT**
- Current clinical trial model **no longer fit for purpose**
- Delivering **transformative care**
- Rather than Preserving the status quo

- **Practice changing**
- Herceptin in erbB2 positive breast cancer
- Glivec in CML
- **BUT**
- **Enthusiasm tempered** by increasing **costs**

- **Survey** the landscape
- **Highlight** health economic **issues**
- **Suggest** cost effective **solutions**

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Editorial

Charting the course for a new cancer clinical research culture in Europe – the need for transformative change

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- **Challenge a series of stakeholders to respond to the title “Cancer Clinical Trials; Changing the Paradigm”**

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- Randomised Clinical Trial
- Bedrock for practice changing clinical care
- **HOWEVER**
- **Is the traditional Regimen A V Regimen B approach appropriate to the era of personalised medicine?**

- Address the **needs** of **all stakeholders** in a comprehensive and transparent fashion
- Set the **efficacy bars** much higher
- **Link efficacy to cost**
  - more efficacy = better opportunity for higher pricing
  - less efficacy = lower price

- **Harmonisation** and **cost efficiencies** at a European level can empower more equitable price negotiations
- Translates to **more equitable access** to innovative therapy for cancer patients.
- Need for a **well-defined biomarker** strategy
- Must be **embedded** into the clinical study process
  - appropriate regulatory review
  - implementation based on best international practices.

- Propose a **new framework**
- Derive **maximum benefit** for patients.
- Move away from a “one size fits all approach” to a precision medicine approach,
- Need to adopt the same principle in our clinical trial design

- Framework must be **comprehensive** but **flexible**
- Addressing **relevant issues** such as
  - clinical trial access
  - biomarker validation and integration,
  - complex data challenges (both technical and ethical),
  - regulatory landscape
  - cost versus value rubicon
  - most importantly the views and experiences of patients

- **Fit for purpose** clinical research **framework** in the era of personalised medicine
- **Must** also be **collaborative**
- Bringing together all relevant stakeholders
- Health care professionals, patients, researchers, bioindustry, payers, policy makers, and regulators),
- **Added value** partnership
- Allow **barriers** to be addressed
- **Solutions** that deliver **optimal cost effective care** for cancer patients