



CDDF MULTI-STAKEHOLDER WORKSHOP
BIOMARKERS AND PATIENTS' ACCESS TO PERSONALIZED
ONCOLOGY DRUGS IN EUROPE

24-25 September 2018
Brussels, Belgium



Pioneering precision medicine

Oxford Cancer Biomarkers

Challenges for Access to Biomarkers

September 2018



Business Confidential

Oxford Cancer Biomarkers

Oxford University spin-out with proven capability to develop, validate and commercialise innovative, clinically important biomarkers

- ⚙ Access to facilities on the Oxford Science Park, UK and Ningbo China
- ⚙ Precision medicine biomarkers powered by artificial intelligence commencing with colorectal cancer



THE OXFORD
SCIENCE PARK

UNIVERSITY OF
OXFORD



2012
Founded

2018
First products
launched

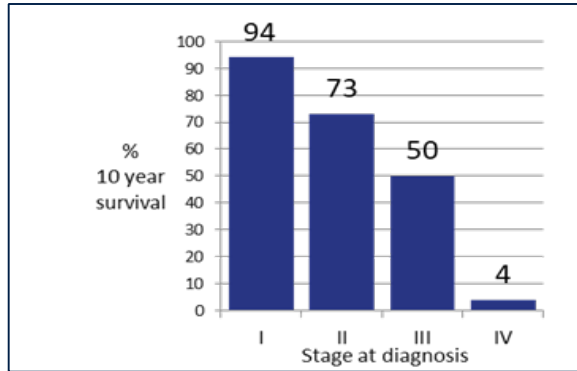
Global product launches
Extend claims and utility
in multiple cancers



Urgent unmet needs in cancer care

Need to expedite earlier detection and improve care pathways

Survival from early stage colon cancer is excellent



- 110,000 lives and £4Bn could be saved in Europe through earlier identification of bowel cancer risk
- Cannot identify Stage II patients at risk of relapse leading to unnecessary overtreatment with chemotherapy

- 0.5-2% people will die from genetic susceptibility to 5FU
- 20-30% suffer severe side effects and hospitalisation



OCB solutions: Precision diagnostic tests

Providing new standards of care
 Screening for colorectal
 cancer



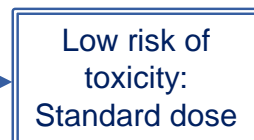
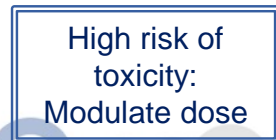
Risk of developing disease
 Integrating into pro-active care package



Risk of recurrence
 Danielsen *et.al.*, Annals of Oncology 2017



Toxic response to drug
 Palles *et al.*, Annals of Oncology 2018



Access to Biomarkers

Diagnostics and Prognostics: Challenges

- ◉ **Access to validated, clinical samples with outcomes**
 - Heterogeneity in population genomics
 - Validation: Real-world evidence

- ◉ **Regulatory approval**
 - Global strategy
 - US Research-Use-Only / FDA submissions
 - UK Multiple stakeholders:
 - NHS
 - NICE
 - MHRA
 - EU/Brexit

- ◉ **Intellectual property**
 - Balance:
 - Academic publications
 - Company investment in R&D and validation



Access to Biomarkers

Screening: Challenges

- ⊗ **Real-World Evidence**
 - Time
 - Cost
 - Availability of clinical samples
- ⊗ **Health economics**
 - Oncologists, Pathologists, Payers
 - Near-term investment for longer-term benefit / joined-up financial-thinking
 - Who pays?
 - Healthcare system
 - Insurance
 - Employee wellbeing
 - Self-pay
- ⊗ **Engagement**
 - Motivation
 - Screening
 - Follow-up
 - Lifestyle change



Access to Biomarkers: Solutions

US model

- ◉ Key Opinion Leader partnerships
 - Start with small number of samples
 - Build and publish
- ◉ Route to fast-track innovation
 - Research-Use-Only can be validated by expert labs
 - Ahead of FDA approval to achieve scale
- ◉ Educational forums
 - Webinars etc



Opportunities to improve care pathways

Collaboration is key

Barrier

- Validated insights
- Adoption
- Funding
- Facilities
- Intellectual property
- Market access

Strategies include

- Academic, Healthcare and corporate partners
- Align with current practice first
- Bootstrap prototype, grants
- Campuses with Accelerators - BioCity
- Judicious filing, deliberate disclosure
- Commence with Key Opinion Leaders, payers, support groups etc



Opportunities to improve care pathways

Multi-disciplinary team approach

- ⊗ Biomarker screening and measurement
 - Molecular
 - Biochemical
 - Body-signs monitoring
 - Requires multi-parameter approach: A.I.
 - Knowledge and data assimilation – inter-relationships
 - Personalised reporting

- ⊗ Lifestyle
 - Patient advocacy
 - Insurers
 - Pharmacy
 - Healthcare providers
 - Employee wellbeing schemes
 - Behaviour change programmes
 - Social media forums



Emergent knowledge application: Epigenetics

Enabling people to take responsibility for their health and wellbeing



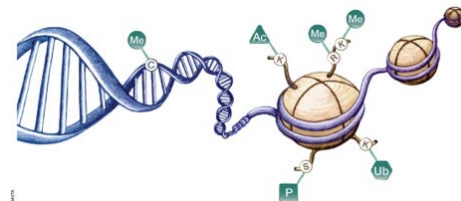
Today – Defeatist

“I have the ...obesity / cancer gene”



Tomorrow – Proactive.....

“My lifestyle choices determine my gene expression”



Opportunity: Translating innovation into pro-active healthcare



Many people wish to take responsibility for the health and wellbeing of themselves and their families through a more informed and proactive approach

Contact

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