Academia–Industry Partnerships: Are we ready for new models of partnership?

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This presentation is based on the publication from D. Lacombe, S. Burock and F. Meunier. Eur J Cancer 2013 Jan;49(1):1-7.
1. Stakeholders in the landscape of drug development
Stakeholders

Patients

Academia
Setting the scientific background

CROs*
Providing services

Industry
Identifying and developing drug

Healthcare providers/payers

* Clinical Research Organizations
Interaction between Industry and CRO

Only a third of all Phase II & III trials completely done in-house.

CRO ➔ 40% of clinical research personnel
• “Ad hoc” approach by assembling institutions around a clinical protocol
• Development of a specific partnership
  – Broader specific research areas
Era of Personalized Medicine

- Translational research
- Biology of disease
- Mechanism of action
- Safety profile
- Efficacy

- Integration of clinical, biological & imaging data
- Change in the clinical trial organization
- New forms of partnership between Academia & Industry
Transparency (<> conflict of interest)
Sustainability
2. Academic Research Organizations (AROs)
Concept of ARO

- A non-profit organization that represents innovative academic collaboration networks in clinical research to boost clinical trials and to establish new standards of care.
- Three large AROs using the same principles of independence
  - NCI (US)
  - NCI (Canada)
  - EORTC
Principles of Independence (1)

- Applicable regardless of the funding source and type of partnership.
- Independent scientific review (Peer Review).
- Independent data management and database handling.
- Independent Data Monitoring Committee (IDMC) and Data and Safety Monitoring Board (DSMB).
Principles of Independence (2)

• Analysis and reporting: all results negative or unfavorable outcome should be reported within a reasonable time frame

• Publication
  – Written according to CONSORT guidelines
  – Authorship pre-defined
New Platform of Research

Complementary added value

Public grants

AROs
Trials for changing practice

Optimal drug development

INDUSTRY
Drug approval
Extension of label
BIOBANKING

1. Sending Tumor tissue
2. Providing clin/path data
3. Centralizing and storing samples
   Extracting gDNA/RNA
4. Sending gDNA/cDNA
5. Performing BM analyses
6. Providing BM results
7. Answering if patient eligible for BM-CT

CLINICAL CENTERS

Treating and recruiting patients

EORTC Headquarters

Enrollment

BM Protocols

DIAGNOSTICS LABORATORIES

Performing BM analyses

Providing Quality Control data

Sending-back tissue (if requested)

EORTC

The future of cancer therapy
3. Expected benefits for new form of academia–industry partnerships in the era of personalized medicine
Expected Benefits

• ↓ High attrition rate
• ↓ Futile exposition of patients to ineffective investigational drugs
• Improvement of trial infrastructure
• Improvement of resources allocation
Areas of Cooperation

Screening of prognostic/predictive biomarkers

Accelerated approval of drug

Validation of assays for biomarkers
  Companion diagnostics

Combination of drugs
  Combined modality treatment

Biomedical imaging
4. Recommendations for an optimal responsibility-split for academia–CRO–industry partnerships
Responsibility-Split

Pharmaceutical Industry
- Drug and assay development
- Drug supply
- Marketing

CRO
- Site management
- Site training
- On site monitoring
- Drug supply process
- Management of biological samples

Study Conduct
- Site selection

ARO
- Trial design
- Data management
- IDMC
- Statistical analysis
- Reporting
- Publication
Up until now, EORTC has been focused on:

- Clinical phase II and phase III trials
- Translational research and correlative science largely retrospective
- Quality assurance programs

Drug development and clinical research landscape of today is evolving
Early clinical trials (R&D)
- Biology / imaging driven
- Integrated TR
- Screening platforms
- Collection of high quality data from various sources
- Sophisticated trials

Pivotal trials
- Highly targeted
- Large differences

Population based studies
- Real world data
- Quality of Life
- Outcomes research
- Health economics
- High Technology assessment (HTAs)
- Pragmatic trials

Urgent to re-shape interactions between stakeholders
New models of partnerships

From trial “designed to learn” to real life situation
Thank you!

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