1. EANM activities IB front

**European Association of Nuclear Medicine**

EANM Research Ltd (EARL):
initiative to promote multicentre nuclear medicine and research
EARL participating scanners 2011-mid 2014

Courtesy Sabine Ettinger, EANM-EARL, May 2014
Trial support via EANM EARL (website May 17th, 2014)

1. RegARd-C
   Study: Phase 2; Regorafenib Assessment in Refractory Advanced Colorectal Cancer
   Intervention: Drug: regorafenib

2. Firstmappp
   Study: Phase 2; First Int’l Randomized Study in Malignant Progressive Pheochromocytoma and Paraganglioma
   Intervention: Drug: Sunitinib

3. EORTC 90111-24111
   Study: Phase 2; Neoadjuvant Afatinib Window Study in Squamous Cell Carcinoma of the Head and Neck
European Initiative for PET as an Imaging Biomarker (EPIB)

August 2010: inter-committee working group on imaging biomarkers (EANM Oncology, Translational Molecular Imaging, Physics, Radiopharmacy and Drug Development Committees)

Aims: raise awareness and enforce acceptance and legislation of PET as imaging biomarker.

define use of imaging biomarkers in drug development, as surrogate endpoints and/or early therapy response markers.

Imaging agents developed in concert with drug development have a built-in synergy that accelerates the drug development process.

FDG PET-CT has been established as a response biomarker for monitoring cancer therapies.

Furthermore, several other radiopharmaceuticals have the potential to monitor response to therapy before, during or after therapeutic intervention.

Update 2014: “no progress, lack of funding”

2. Lessons from rowing & Higgs

need for paradigm shift in scientific collaboration
The case of 18F-FDG PET as a biomarker of response to cancer therapy

1. 1989 first clinical applications
2. 1999-2009 response taxonomy / guideline
   - 1999 EORTC, 2009 PERCIST
   - 2007 IHP Lymphoma, 2014: 2.0 in press
   - single & multicenter
   - 2012 meta-analysis
   - 2014: update via RECIST?
4. 2006-2010 quantitative standardisation & study design
5. 1989-2014 many observational studies
   - tumors
   - interventions
   - timing PET
   - methodology PET
   - 2010-4: standards of reporting?
The case of 18F-FDG PET as a biomarker of response to cancer therapy

1. 1989- clinical applications
2. 1999-2009 response taxonomy / guideline
   - 1999 EORTC
   - 2007 IHP Lymphoma
   - 2009 PERCIST
3. 2006-2010 quantitative standardisation & study design
4. 1995-2014 repeatability & single center to multicenter
   - 2012 meta-analysis
5. 1989-2014 many observational studies
   - tumors
   - interventions
   - timing PET
   - methodology PET
6. 2009: RECIST 1.1: no quantitative 18F-FDG PET
   - IB
   - responsiveness
   - QA/QC
7. 2014: standards of reporting ?
Revolution in brain science demands Higgs Boson-type collaboration
Individual patient data meta-analysis (IPD-M) including re-analysis

1. Collaborative mind-set: published data
2. Governance & “Rules of engagement”
3. IRB issues
4. IT infrastructure
5. Model: network of existing data-analysis labs?
6. Funding
Individual patient data meta-analysis (IPD-M) including re-analysis

1. Collaborative mind-set: *published data*
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**PETRA-NHL**: PET Re-Analysis in Non-Hodgkin’s Lymphoma

Domain: accuracy of interim 18F-FDG PET in 1st line treatment

Model: IPD-M

2014: 3 yrs project funded by Dutch Cancer Society

Initial consortium: NL, UK, F, D [US pending]

**next: PETRA – SOLID?**