EARL FDG-PET/CT Accreditation

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The EARL FDG-PET/CT accreditation programme was established in 2010 on the basis of the guidelines of the European Association of Nuclear Medicine (EANM). Its aim is to ensure comparable performance of PET/CT systems within multicentre setting by harmonising acquisition and interpretation of PET/CT scans. The accreditation programme is run by the EANM Research Ltd (EARL) and provides independent quality control/assurance within multicentre clinical trials. This programme is already fully established, scientifically validated, and proven to address the need of pharmaceutical industry regarding harmonisation and standardisation. Up to now, 65 centres within Europe are participating in this program.

Imaging biomarkers in drug development:

- Functional and molecular imaging biomarkers (IBs), e.g. FDG, FLT, accelerate drug development by detecting drug activity and measuring efficacy. Same imaging modality should be applied across subsequent phases of compound studying.
- Predictive IBs can assist in early Go/No go decisions and are used to assess effect of drug activity.
- Prognostic biomarkers are used to predict negative/positive outcomes and facilitate patient stratification.

Benefits of FDG-PET/CT accreditation in drug development:

- EARL´s know-how is based on worldwide-recognised imaging experts, with a global leading role in PET/CT research, who provide advice within the program and monitor its development.
- The pre-requisite for evaluation of imaging results within pre-clinical and clinical trials is comparable scanner performance across multiple sites (reducing inter/intra institute variability in SUV results; providing lower/upper limits of RCs; calibration factor within -/+10%), which is fundament of the EARL accreditation: results can be compared, exchanged and combined.
- Accurate, reproducible and quantitative assessment enabled through standardisation of methodology including patient preparation, scan acquisition, image processing and analysis.
- Reliable and quantitative IBs results generated within multicentre clinical trials, leading to an enhanced outcome (e.g. information on biologic/pathological processes and response to therapeutic intervention), thus accelerating compound development and approval by the regulatory agencies and lowering cost on the long run.

At the back please find real example data

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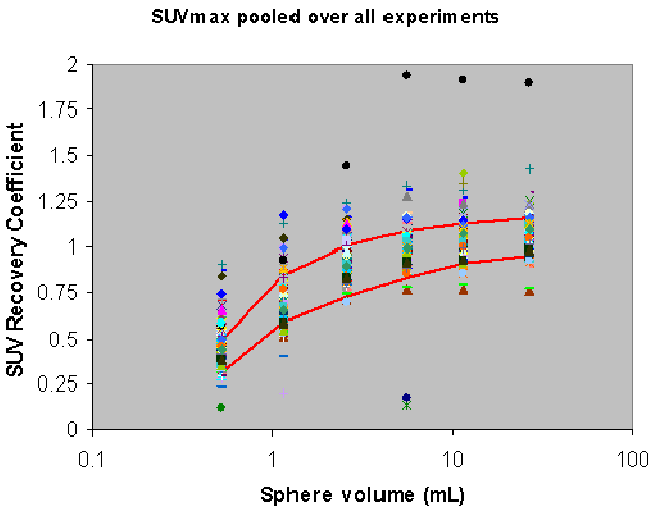

Figure 1: Results of SUV Recovery Coefficients (RCs) from 55 PET/CT systems <u>before</u> EARL FDG-PET/CT accreditation: A high SUVmax RCs variability between sites is shown (no vendors indicated). A clear contrast with the results in figure 2 can be seen, indicating the need for a harmonising PET/CT scanner accreditation programme as performed by EARL.

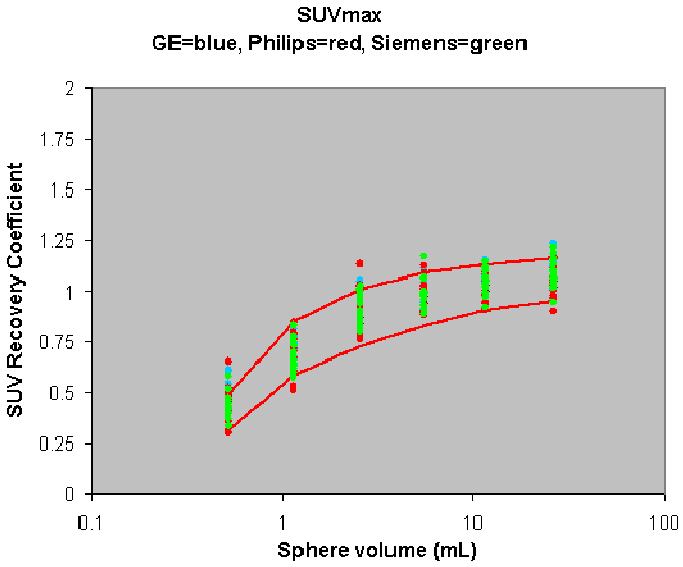

Figure 2: Results of SUV RCs from 55 PET/CT systems <u>after</u> EARL FDG-PET/CT accreditation: A clear reduction in SUVmax RCs variability between sites and scanner types is shown. EARL accreditation minimises scanner performance variability and enhances quantitative imaging accuracy and precision. Furthermore it is illustrated that all PET/CT vendors can comply with EARL standards.

References:

- The presentation from Prof. Ronald Boellaard including the graphs above can be found at: http://earl.eanm.org → Projects → FDG-PET/CT Accreditation → Guidelines/Publications
- Boellaard R et al. Initial experience with the EANM accreditation procedure of FDG PET/CT devices. Eur. J. Cancer 2011; 47 (Suppl. 4):S8
- Boellaard R et al. FDG PET and PET/CT: EANM procedure guidelines for tumour PET imaging: version 1.0. Eur J Nucl Med Mol Imaging 2010; 37(1):181-200

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