

RESEARCH 4 LIFE[®]

an  initiative

The EARL & EARL accreditation

EARL · EANM Forschungs GmbH / EANM Research Ltd. · Hollandstrasse 14 / Mezzanine · 1020 Vienna, Austria
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Austrian Registry of Corporations: FN 291161d · VAT-ID No. in Austria: ATU 63436026

Quantitative imaging biomarker

Requirements for (quantitative) imaging biomarkers:

- Repeatability (in one patient using the same PET/CT system)
- Reproducibility (between patients, systems and institutions) of performance, analysis and interpretation

standardisation & harmonisation of imaging procedures essential

PET imaging / SUV uncertainties



$$SUV_{TBW} = \frac{c_t [kBq/ml]}{Dose[MBq]/weight[kg]}$$

Technical factors

- Relative calibration between PET scanner and dose calibrator (10%)
- Residual activity in syringe (5%)
- Incorrect synchronization of clocks (10%)
- Injection vs calibration time (10%)
- Quality of administration (50%)

Physics related factors

- Scan acquisition parameters (15%)
- Image reconstruction parameters (30%)
- Use of contrast agents (15%)
- ROI (50%)

Biological factors

- Uptake period (15%)
- Patient motion and breathing (30%)
- Blood glucose levels (15%)
- Changes in blood clearance

FDG PET and PET/CT: EANM Procedure Guidelines for Tumour PET Imaging (trials and practice)

2010: version 1.0

2015: version 2.0

EARL accreditation

Main aim:

facilitate quantitative (SUV) evaluation of PET/CT
within multi-centre studies.

EARL accreditation

Multicentre setting (Accreditation)

- Standardisation of acquisition and processing of patient studies
- Rigorous harmonisation of the imaging systems
 - Compare
 - Exchange
 - Combine findings
- Reduction in inter-/intra-institute variability

EARL FDG-PET/CT accreditation

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EARL FDG-PET/CT accreditation programme

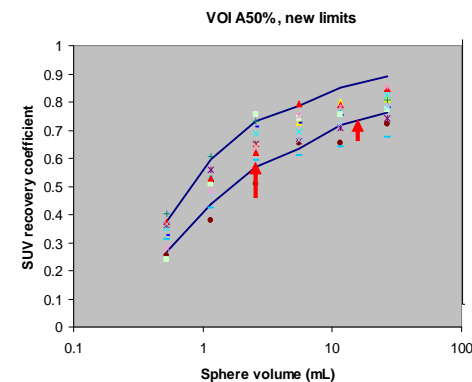
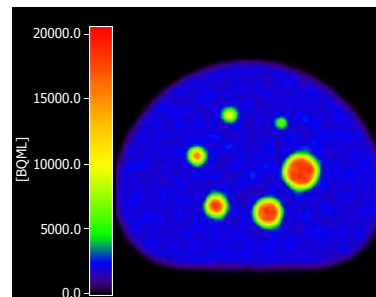
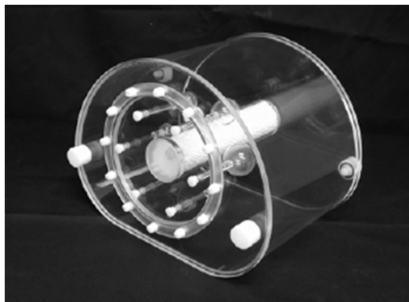
- Independent quality control/assurance
- Comparable scanner performance across multiple sites
- Essential quality assurance **in daily clinical practice** as well as high eligibility as a participant in multicentre trials

Multi-center QC and calibration

- Daily QC conform standard procedure of system / manufacturer
- Calibration QC using (cylindrical) phantom (15-30cm diameter)
- “Adjusted” NEMA NU 2-2001 Image Quality procedure/measurement to measure recovery coefficients as function of sphere size (= ‘effective image resolution’)
- CT-QC cf recommendations of ESR/national law
- Misc. QC (e.g. for scales, alignment etc)
- Detailed description in EANM guideline v1.0 and v2.0 (2015)

Multi-center QC and calibration

- Calibration QC specification:
 - maximum allowable calibration deviation = + or – 10% (global)
- SUV recovery specifications:
 - for SUVmax (focus –as SUVmax is used clinically!)
 - for SUVmean



Variation of system performance, quality control standards and adherence to international FDG-PET/CT imaging guidelines

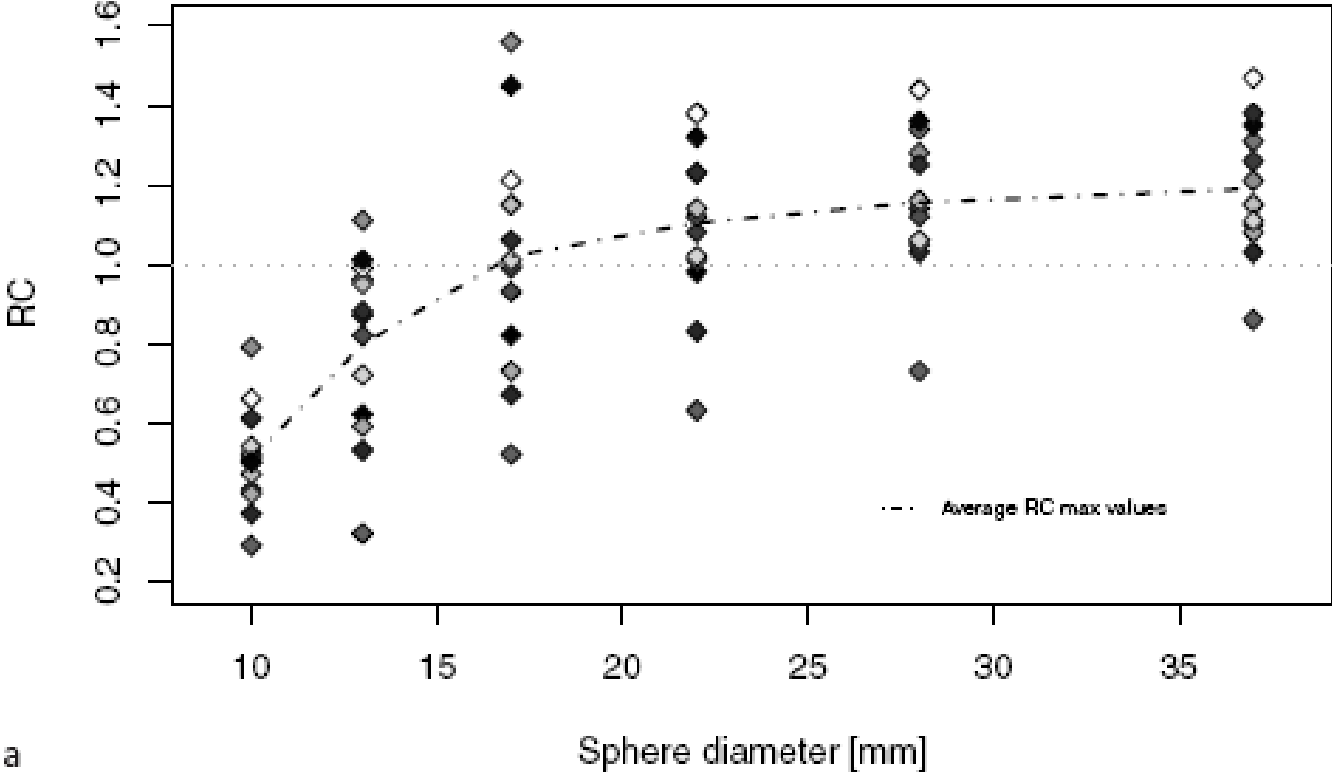
A national survey of PET/CT operations in Austria

I. Rausch^{1,2}; H. Bergmann¹; B. Geist²; M. Schaffarich¹; A. Hirtl²; M. Hacker²; T. Beyer¹

¹Centre for Medical Physics and Biomedical Engineering, Medical University of Vienna, Austria; ²Division of Nuclear Medicine, Department of Biomedical Imaging and Image-guided Therapy, Medical University of Vienna, Austria



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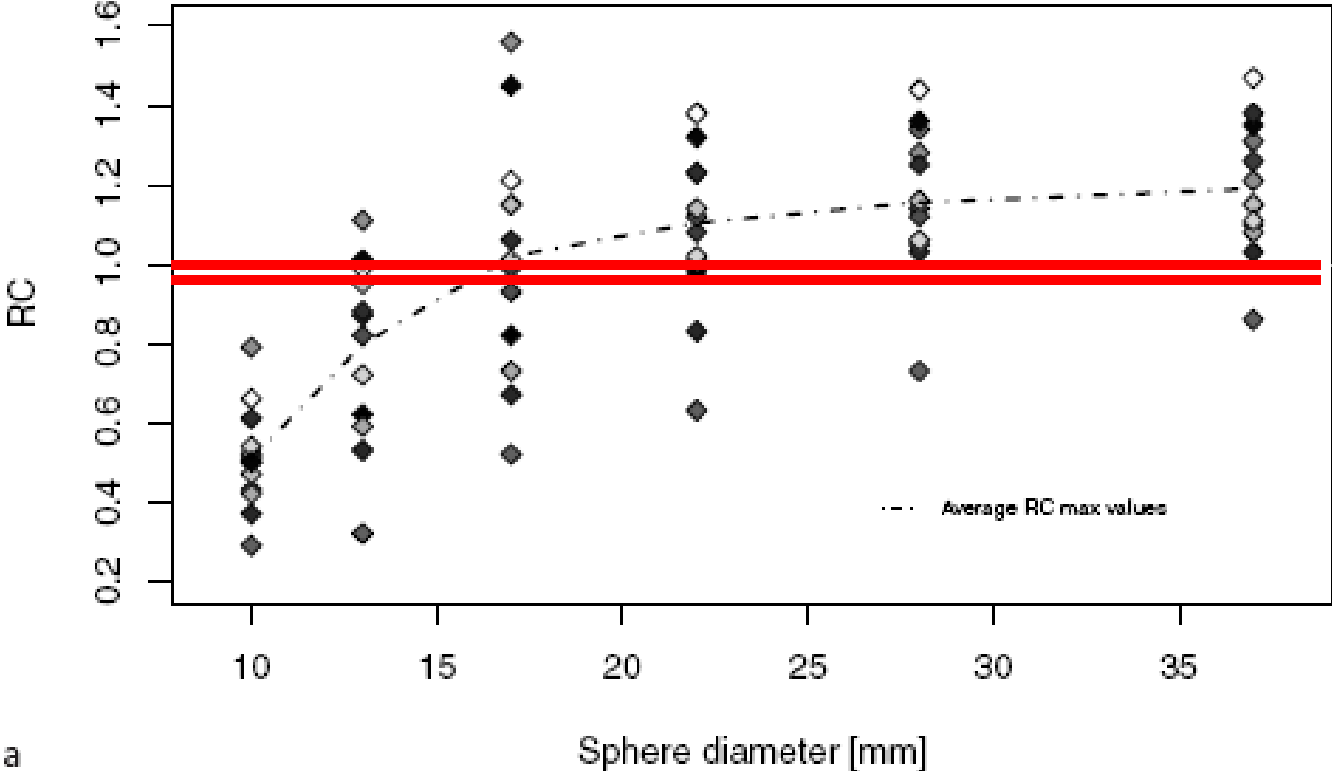
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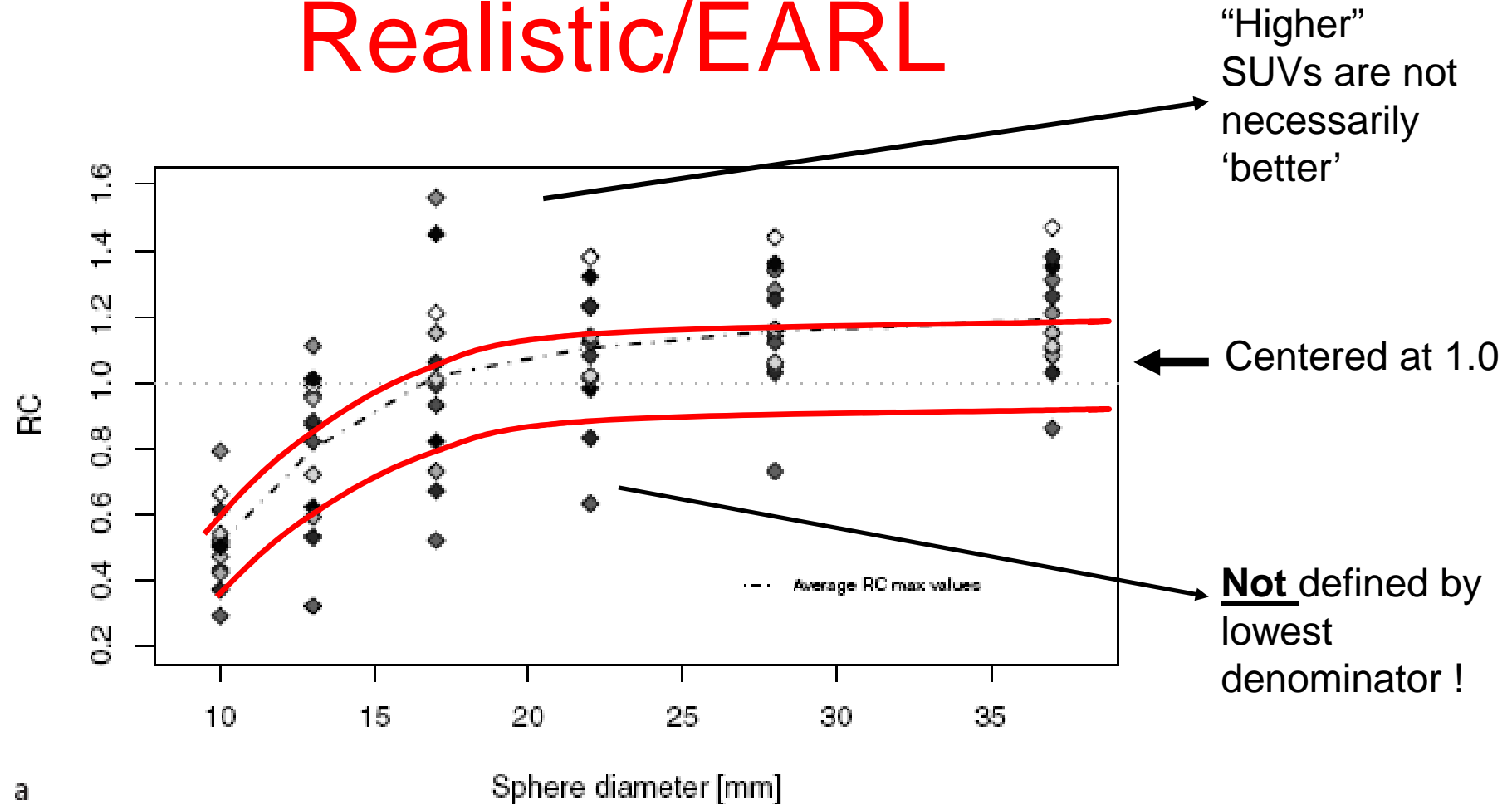


IDEAL



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Realistic/EARL



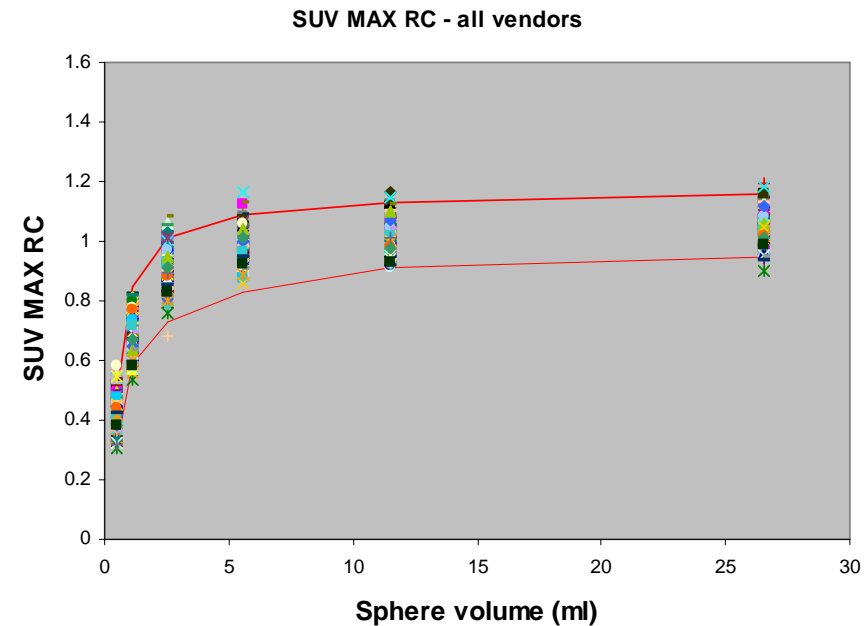
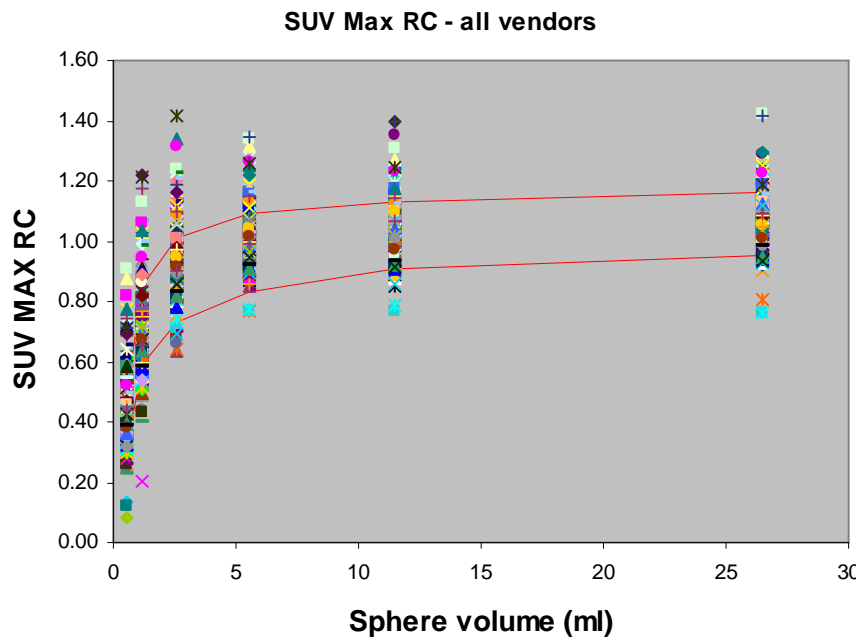
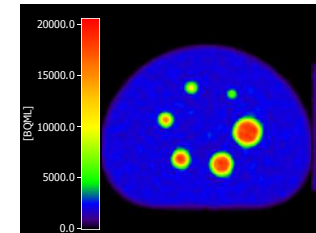
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Multi-center harmonization of quantification

Image Quality % SUV recovery


Results at first test...

...accredited sites



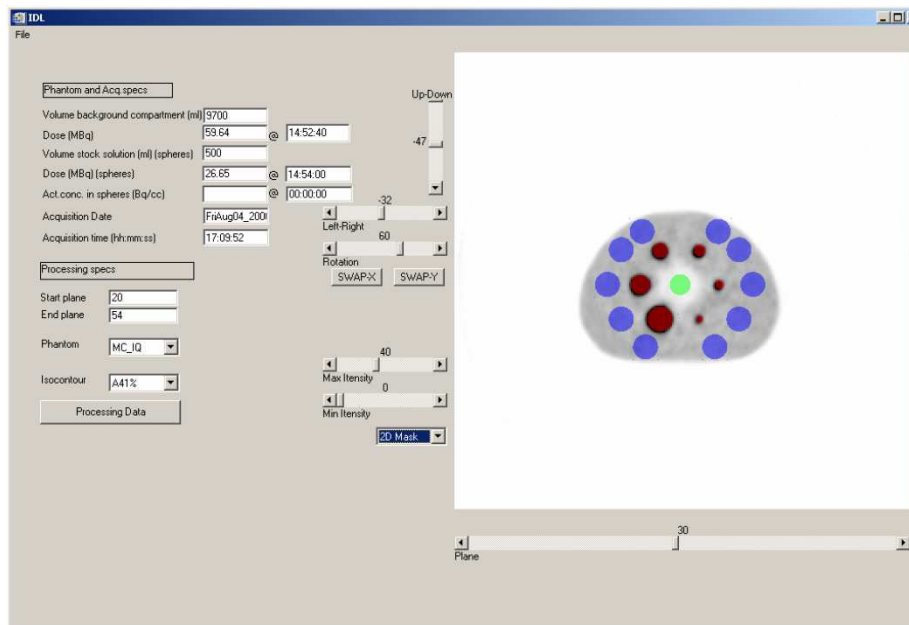
Comparable SUV recovery among sites and vendors is feasible (n=>65)

Accreditation: current status..

- Web portal for uploading QC data established
- SW tools for semi-automated analysis of results
- Semi-automated storage of results in dbase
- First pilot (n=12) successfully completed in March 2011
- At present ~100 sites accredited
- Accredited sites are listed on EARL site
- Signet: 
- Program formally endorsed by EORTC & EATRIS

European accreditation program EARL, EANM, EORTC

Standardised software tools for analysis and interpretation of QC experiments were developed:



Calibration QC:

- Automatic VOI placement
- Verification of calibration
- Verification of inter-&intra-plane uniformity

IQ QC

- Recovery coefficients (volume & act.conc.)
- Cold spot recovery using central insert (scatter)
- Verification of calibration using back ground VOI

How to get accredited (1) ?

- Express interest through EARL website
- Sign written agreement to comply with guideline (GL)
- Fill out online questionnaire
information on PET/CT systems, DC, wellcounters, SW etc
- Perform QC experiments as described in GL
 - Manual
 - SOP for calibration QC
 - SOP for image quality/SUV recovery QC

How to get accredited (2) ?

- Submit image data and report forms to EARL
 - Please keep raw projection on your system till receipt of approval
- QC data will be centrally analysed by EARL
 - see next slide for criteria/specs
- If not approved, additional reconstructions may be requested
- When results are with specs:
 - approval is granted and signet may be used
- Save approved acquisition and reconstruction protocol/settings as “EARL STD” protocol. This protocol should be used in any multicenter study (and is required for participation in EORTC trials)



On-going accreditation procedure

Accreditation/re-accreditation

- Calibration QC: 4 times a year
- Image QC: 1 time a year
- Reconstruction of calibration QC and image QC data with EARL approved settings
- Accredited sites are listed at EARL website
- Accredited sites may use signet
- Accreditation fee: 1000 Euro per system per year
- Video demonstrating how to perform the experiments

Certificate

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EARL FDG PET/CT accreditation << JAHR >>

This is to certify that the

>> CENTRE X <<

>> SCANNER Y <<

ev. >> SCANNER Z <<

is granted accreditation according to the requirements and specifications indicated in the EANM guidelines (FDG PET and PET/CT: EANM procedure guidelines for tumour PET imaging": version 1.0). FDG PET/CT accreditation ensures similar performance of PET/CT systems within a multicentre setting by harmonising acquisition and interpretation of PET/CT scans. Accredited PET/CT centres of excellence can compare, exchange and combine FDG PET/CT findings, including SUVs, since data are collected and processed in a standardised manner. *The regular submission and approval of QC data, as required by EARL, is a condition for the maintenance of the accreditation.*

Vienna, mm dd, yyyy 

Prof. Dr. Klaus Tatsch
CEO of EARL

Andrea Bauer, M.A.
CEO of EARL



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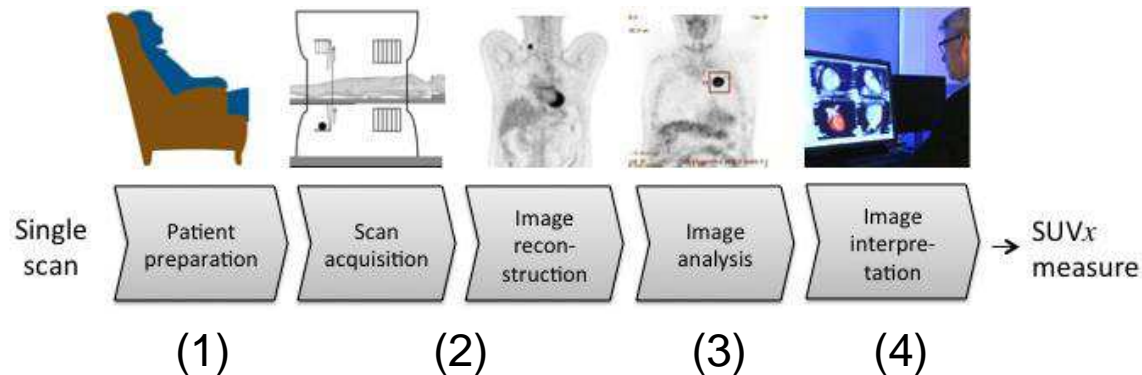
.....and now beyond SUV:

- MATV
- TLG
- Heterogeneity
-
-



need strategy to avoid heterogeneity in research
to avoid running into the same problems as with SUV
so that trial data can be pooled to substantiate evidence

Basic principle is similar for most (PET based) imaging biomarkers



Standardisation/harmonization implies:

1. Guidelines or imaging procedures to address user/observer related factors (uptake time, patient preparation, data analysis/intepretation)
2. Requirements for image data acquisition (activity, scan acquisition parameters, reconstruction settings)
3. Rules for image/data analysis
4. Criteria for data (e.g. response) intepretation

Other developments

Quality in NM – FDG PET/CT – related documents

- UPICT – Uniformity of Protocols in Clinical Trials:
 - Graham M et al. J Nucl Med 2015
- QIBA (Quantitative Imaging Biomarker Alliance) FDG PET/CT Profile:
 - addresses performance and compliance criteria (systems and users)
 - online available at RSNA/QIBA
- EANM/SNMMI FDG PET/CT guideline version 2.0 (EJNMMI 2015)