EARL at a Glance: History, Projects, Visions
30.10.2012 EANM‘12
EANM founded the EANM Research Ltd in 2006 (Nominal capital of € 35,000)

EANM is 100% shareholder

Rationale: Liability

CEOs

A. Bauer
K. Tatsch
EARL at a Glance

EARL was created to unleash the power of molecular imaging and further:

- To improve nuclear medicine and its practice within the European Union
- To provide a basis for discussion and the exchange of cutting edge ideas
- To act as a contact point for researchers as well as for clinicians and business leaders
- To provide a platform for the efficient pursuit of scientific initiatives
- To facilitate multicentric research projects
- To enhance the comparability of data acquired by molecular imaging
- To boost molecular imaging so that it becomes a standard diagnostic modality in future clinical medicine and research
- To position nuclear medicine within the EU research agenda
CEOs report to EANM Executive Committee

Committees (Networks of Excellence, NoEs)
ENC-DAT study


• 13 centers in 10 European countries
• Multicenter cross-calibration
• Standardized evaluation by core labs
Rationale ENC-DAT study:
Overcome limitations due to:

- Lack of standardization
- camera performance
- acquisition parameters
- processing
- quantification

Lack of reference data base of healthy controls
- age corrected
- gender values

DaTSCAN SPECT:
In clinical practice and clinical trials the quality spectrum of scans ranges from excellent to nondiagnostic.
ENC-DAT study part 1: Quality control of imaging device

Gamma camera-certification (1 expert physicist)
Initial:
- I-123 intrinsic uniformity
- System uniformity with Co-57
- System sensitivity with I-123
- Quantitative SPECT resolution with I-123
- Qualitative resolution planar
- COR
- Antropomorphic 3D striatal-phantom

Periodically:
- System uniformity with Co-57
- COR
ENC-DAT study part 2: Phantom measurements

Cross calibration between camera systems

TRUE = 1.0139 * measured

$R^2 = 0.9844$
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ENC-DAT study: Recruitment

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ENC-DAT study part 3: Healthy subjects

- No history of parkinsonism in first-degree relatives
- No medication known to affect DAT binding
- UPDRS score: < 60 yrs = 0; ≥ 60 yrs ≤ 5
- SCL-90-R score < 63
- BDI score ≤ 9
- MMSE ≥ 28
- Negative urine based screening for drug abuse (10 drugs)
- Edinburgh Handedness Test
- Copenhagen Smoking Questionnaire
- MRI: < 60 yrs ARWMC score 0; > 60 yrs score ≤ 2
ENC-DAT study part 3: Healthy subjects
ENC-DAT study part 3: Healthy subjects
- World’s largest normal database of FP-CIT scans
- 152 subjects, 20 to 90 yrs
- Balanced gender
- Intensive neurological/neuropsychiatric evaluations
- MRI scans
- Highly significant relationship between DAT binding and age (decline per decade: 4.6%)
ENC-DAT study outcome

- The normal database established by this project is a valuable benchmark for Nuclear Medicine centres performing neuroimaging studies.
- Database was sold to GEHC and HERMES (further companies have expressed interest).
- Study data are available (online) for scientific projects of participating sites (n > 10).
- Publications can be found on [http://earl.eanm.org](http://earl.eanm.org)
ENC-DAT Publications: Group


ENC-DAT Publications: Center-Based Projects


GE-HC: Quantification based on ENCDAT: DaTQUANT

- DaTSCAN template of healthy controls from ENCDAT
- MNI space
- VOI map (S,C,P,AP,PP)
- Co-registration
- SBR
- P/C
- Asymmetry
Hermes: Quantification with ENC-DAT BRASS

- DaTSCAN template of healthy controls from ENCDAT
- MNI space
- VOI map
- Co-registration
- SBR
- P/C, PP/AP/C
- Pixelwise comp.
- Age corrected reference values
- Camera specific
EARL offers a service of „calibration of gamma cameras for ENC-DAT“. An expert physicist comes to calibrate the equipment in the individual department in the same way as done for the ENC-DAT project. Thus, the departments’ measurements can easily be compared with the normal database of the DaTSCAN project.
Accreditation program

- Quality standard: FDG-PET and PET/CT – EANM procedure guidelines for tumour PET imaging (version 1.0)
- Online questionnaire
- Quarterly calibration quality control (QC) and annual image quality QC
- Europe-wide

PET/CT systems are operated quantitatively and have a similar performance in a multicenter setting.
EARL: accreditation of imaging sites for EORTC Trial

- EORTC Imaging Group (S. Stroobants)
- Accreditation of 11 sites in D, NL, B, F
- EORTC will only allow accredited imaging centers to participate in their trials

- MoU between EANM/EORTC:
  a) incorporating PET/CT in clinical trials from the very beginning
  b) quality standard
EARN FDG-PET/CT Accreditation

- **EARN**: accreditation of imaging sites in NM

  - First step: EARN asked 60 top imaging centers in Europe to accredit themselves (EARN charges € 1000.- service fee)
  
  - Second phase: EARN aims at asking all NM departments in Europe to accredit themselves
  
  - Benefit for the centers: they can join oncological research projects and sites are published on the EARN/EANM website as PET/CT accredited sites; certificate; quality label for machine
EPIB (European initiative for PET as Imaging Biomarker)

- Inter-Committee working group was set up in 2010
  (Representatives of the Oncology, Translational Molecular Imaging, Radiopharmacy and Drug Development Committees)

- To raise awareness and enforce acceptance and legislation of PET as Imaging Biomarker

- EU is just beginning to consider the topic „biomarkers“
Taskforce-EU Grants

- Created in June 2011
- Aim: to raise awareness within the nuclear medicine community of the necessity of competing for EU research grants as well as conducting multicentre studies.
- Main objectives:
  - To boost the role of molecular imaging in personalised medicine
  - To make the European Union (EU) aware of research topics in nuclear medicine which will be pivotal in the future
  - To follow open calls from the EU and the development of recent grants in order to develop opportunities for nuclear medicine
EANM is shareholder of EIBIR

(European Institute for Biomedical Imaging Research)

K. Tatsch is official representative of EANM at EIBIR

• PEDDOSE.NET (2010)

„Dosimetry and Health Effects of Diagnostic Applications of Radiopharmaceuticals with particular emphasis on the use in children and adolescents.“
PEDDOSE.NET (2010) Objectives:

- Summary and evaluation of current knowledge on the impact on patients' health of small and non- or little-repetitive doses (amounts) of radioactive, biological and/or chemical substances, as currently used in diagnostic imaging procedures
- Development of recommendations and guidelines to drive scientific and technologic innovation to improve patient healthcare in med. imaging
- Identification, if clinical studies are needed, and corresponding detailing of the studies
- Involvement of people in legislative approval of these agents for human use

Aim: Development of recommendations and guidelines
MEDRAPET (2010)

„Study on the Implementation of the Medical Exposure Directives Requirements on Radiation Protection Training of Medical Professionals in the European Union.“

• The results of the 27-months project will form the basis for the revision of the Radiation Protection 116 Guidelines on Education and Training in Radiation Protection for Medical Exposures.

• Aim is to provide an improved implementation of the Medical Exposure Directive provisions related to radiation protection education and training of medical professionals in the EU Member States.
Complementing / implementing EANM vision of “going clinical”

Extend FDG PET/CT accreditation to NM in whole of Europe

Raise awareness with “big pharma” / CROs of the importance of standardization of imaging

Relevance of multicentre trials for innovative radiopharmaceuticals
What can EARL do for you:

- provide an extensive network of excellent professionals in the field of nuclear medicine.
- facilitate your clinical (multicentric) study. EARL works closely together with the principal investigator (PI) as well as the contract research organization (CRO).
- provide a platform for scientific initiatives.
What can EARL do your you:

- open to cutting edge ideas – requests for academic/commercial research projects can be directed to EARL.
- ready to accept project proposals from nuclear medicine stakeholders, preferentially in the following priority fields: Cardiology, Drug & Radiopharmaceutical Development, Neurology/Psychiatry, Oncology, Paediatrics, and Radionuclide Therapy.
Create a Win-Win situation by financial support of EARL:

Associate your Company’s name with the future of molecular imaging now, and harvest the fruits of your commitment soon, by:

- Increasing the use of molecular imaging in clinical medicine
- Accelerating the development of new radiopharmaceuticals
- Stimulating multicentre drug development and biomedical research
- Ultimately increasing your sales in nuclear medicine

For discussion of individual models of support or further information please contact EARL.