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Jean-Paul Vallée

Co-opted Members
Peter Brader
Nicolas Grenier
Overview

- Position paper (Insights into Imaging)
- Collaboration (EORTC, EIBIR, WG personalized Medicine, ESMOFIR)
- Educational activities (ECR, ESOR)
- ESR Strategy
ESR statement on the stepwise development of imaging biomarkers

European Society of Radiology (ESR)

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Abstract Development of imaging biomarkers is a structured process in which new biomarkers are discovered, verified, validated and qualified against biological processes and clinical end-points. The validation process not only concerns the determination of the sensitivity and specificity but also the measurement of reproducibility. Reproducibility assessments and standardisation of the acquisition and data analysis methods are crucial when imaging biomarkers are used in multicentre trials for assessing response to treatment. Quality control in multicentre trials can be performed with the use of imaging phantoms. The cost-effectiveness of imaging biomarkers also needs to be determined. A lot of imaging biomarkers are being developed, but there are still unmet needs—for example, in the detection of tumour invasiveness.

Main Messages
• Using imaging biomarkers to streamline drug discovery

Introduction

There is increasing interest in developing the quantitative imaging of biomarkers in personalised medicine. Biomarkers are defined as “characteristics that are objectively measured and evaluated as indicators of normal biological processes, pathological processes, or pharmaceutical responses to a therapeutic intervention” [1]. Broadly, biomarkers fall into two categories: bio-specimen biomarkers, including molecular biomarkers and genetic biomarkers, and bio-signal biomarkers or imaging biomarkers. Bio-specimen biomarkers are obtained by removing a sample from a patient. Examples of these molecular biomarkers are genes and proteins detected from fluids or tissue samples. Bio-signal biomarkers remove no material from the patient, but rather detect and analyse an electromagnetic, photonic or acoustic signal emitted by the patient [2]. These imaging biomarkers have the advantage of
Collaborations

- European Organization of Research and Therapy of Cancer (EORTC)
- European Institute for Biomedical Imaging Research (EIBIR)
- Working Group on Personalized Medicine within the ESR Research Committee Board
- European Society of Molecular and Functional Imaging in Radiology (ESMOFIR)

And of course with you!
EORTC has performed 70,000 patients within the last 10 years, 30 multicenter studies per year.

Imaging Group (chair: Nandita deSouza - radiologists, nuclear medical physicians, physicists, and imaging scientists) is part of the "translational research initiative" within EORTC.

Imaging protocols that are acceptable for a number of sites were established and a programme of quality assurance/quality control was implemented prior to imaging in multicentre trials.
To date, six imaging studies are ongoing with molecular imaging (PET) and advanced MR techniques, with another four studies coming online next year. Data are being centralized for central review.

Pilot studies for PET accreditation with EANM were launched and diffusion MR standardization via QuIC-ConCePT (IMI project) was established in collaboration with QIBA-RSNA.
# EORTC IMAGING GROUP MEETING
2 September 2013, Tagnon Meeting Room, EORTC Headquarters

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Participants</th>
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<tbody>
<tr>
<td>11:00 – 16:30</td>
<td><strong>Imaging Group Meeting</strong></td>
<td><strong>IG Members</strong></td>
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<tr>
<td>11:00 – 11:15</td>
<td>Welcome: Imaging group achievements and future strategy</td>
<td>N. de Souza</td>
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<td></td>
<td>- Membership</td>
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<td>- Central review committee</td>
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<td></td>
<td>- Young investigator</td>
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<td></td>
<td>- EORTC-QIBA symposium at ISMRM 2014</td>
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<tr>
<td>11:15 – 11:45</td>
<td>Road maps to new strategies: EORTC-SPECTA forum</td>
<td>EORTC HQ team</td>
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<tr>
<td>11:45- 12:45</td>
<td>QuIC-ConCePT: technical/biological validation studies (MR-diffusion imaging and FLT-PET)</td>
<td>Young investigators</td>
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<td></td>
<td>Discussion</td>
<td>S. Stroobants</td>
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<td>N. de Souza</td>
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<tr>
<td>12:45-13:30</td>
<td>Lunch</td>
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<tr>
<td>13:30-14:00</td>
<td>Challenges in implementing diffusion MR in multicenter trials (e.g. 90111-MRI)</td>
<td>J. Winfield</td>
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<td>M. Lemort</td>
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<td>14:00-14:30</td>
<td>Discussion</td>
<td>All</td>
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<tr>
<td>14:30-15:00</td>
<td>Limitations of RECIST? Current PET criteria?-PERCIST? Where should we go?</td>
<td>P. Bourguet</td>
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<tr>
<td>15:00-15:30</td>
<td>Discussion/Debate</td>
<td>All</td>
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<tr>
<td>15:30-16:15</td>
<td>High risk prostate cancer</td>
<td>To be confirmed</td>
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<tr>
<td>16:15-16:30</td>
<td>Finance/ambitions</td>
<td>M. Smits</td>
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**Afternoon session (bone sub-committee)**

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<tr>
<th>Time</th>
<th>Session</th>
<th>Participants</th>
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<tr>
<td>16:30-17:30</td>
<td><strong>Bone sub-committee meeting</strong></td>
<td><strong>Bone members</strong></td>
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<tr>
<td>16:30-17:00</td>
<td>Review paper of bone evaluation</td>
<td>All</td>
</tr>
<tr>
<td>17:00-17:30</td>
<td>Clinical trials on bone evaluation</td>
<td>All</td>
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</tbody>
</table>
- **SPECTAplatforms**

Screening platform on a molecular basis
Biobank – Biomarker analysis – Clinical data
+ **IMAGING DATA**
e.g. FDG-PET related to outcome by pooling the data
QuiC-ConCePT

3 imaging biomarkers:
- FLT-PET (proliferation)
- ICMT-PET (apoptosis)
- DW-MR (early necrosis)

- Are they biological valid? (biological validation)
- Develop standardized acquisition and postprocessing methods (technical validation studies)
European School of Radiology (ESOR)
Course on Imaging Biomarkers

- 2 successful courses were performed (day before ECR 2012/2013, one day course)
- with support of Nick Gourtsoyiannis, Luis Marti-Bonmati and I have prepared a full program with the structure of ESOR
- Sponsoring could be organized by me
- the course will take place on the 5/6th of June 2014 in Barcelona with a limitation of 30 attendees due to availability of 30 workstations in the ESR learning center
Biomarkers: definition and development
L. Martí-Bonmatí, Valencia/ES

Imaging biomarkers: multivariate - multiparametric
A. Alberich, Valencia/ES

Measurements and biases in imaging biomarkers evaluation
J.-P. Vallee, Geneva/CH

Workshops
(L. Martí-Bonmatí, A. Alberich, J.-P. Vallee)

Imaging biomarkers in neurological disease 1 - morphometry
W. van Hecke, Antwerp/BE

Imaging biomarkers in neurological disease 2 – functional
M. Essig, Erlangen/GE

Imaging biomarkers in breast tumours
Th. Helbich, Vienna/A

Workshops
(W. van Hecke, M. Essig, Th. Helbich)
ESOR Course 2014
Quantitative Imaging Biomarkers – ready for clinical application

- Imaging biomarkers in diffuse liver disease
  A. Ba-Ssalamah, Vienna/A

- Imaging biomarkers in disease of the pancreas
  C. Matos, Brussels/BE

- Imaging biomarkers in female pelvis disease
  A. Sahdev, London/UK

- Workshops
  (A. Ba-Ssalamah, C. Matos, A. Sahdev)

- Imaging biomarkers in prostate cancer
  J. Futterer, Nijmegen/NL

- Imaging biomarkers in the musculo-skeletal system – joint structures
  S. Trattnig, Vienna/A

- Workshops
  (J. Futterer, S. Trattnig)
ECR 2014 Special Focus Session
Imaging Biomarkers

- Special Focus Session Imaging Biomarkers in 2014 on Imaging biomarkers in cancer drug development
Special Focus Session ECR 2014: Imaging biomarkers in cancer drug development

Chairman’s introduction
B.E. Van Beers; Clichy/FR
To introduce the general context of imaging biomarkers in drug development.

Qualification of imaging biomarkers in drug development
J. Waterton; Manchester/UK
To describe the steps and hurdles in drug development and the need for imaging biomarkers.
To report on the qualification steps of imaging biomarkers.
To describe the problem of double validation for the use of biomarkers in drug development.

RECIST and beyond
V. Vilgrain; Clichy/FR
To describe the evolution of the WHO and RECIST criteria for tumor response to treatment.
To explain the limitations of the RECIST criteria in the assessment of targeted treatments and the potential of new criteria such as the mRECIST, Choi and EASL criteria.
Special Focus Session ECR 2014:
Imaging biomarkers in cancer drug development

Functional imaging in cancer drug development
N. de Souza; London/UK
To describe the potential role of quantitative imaging of processes related to tumor growth such as cell metabolism, cell death, and vascular function in the assessment of tumor response.
To report on the issues of accuracy, reproducibility and standardization for using functional imaging biomarkers in drug development.

Quantitative nuclear medicine in drug development
A.H. Jacobs; Muenster/DE
To understand the role and limitations of radiolabeled functional and molecular imaging biomarkers in drug development from preclinical to phase 3 clinical phases.
To put into the perspective the role of radiolabeled imaging biomarkers relative to those of other biomarkers in this context.

Panel discussion
What are the new imaging biomarkers at the horizon in drug development?
To discuss which imaging biomarkers are ready as pharmacokinetic/pharmacodynamic biomarkers and as surrogate endpoints.
ECR 2015 Special Focus Session Imaging Biomarkers

- Special Focus Session Imaging Biomarkers in 2015 on Imaging biomarkers in degenerative joint disease
Chairman’s introduction
S. Trattnig; Vienna/A
To introduce the general context of imaging biomarkers in the musculo-skeletal system

Osteoarthritis and cartilage repair – quantitative cartilage imaging
Part 1- proteoglycans – dGEMRIC
E.H.G. Oei, Rotterdamm/N
- To describe the basic principle of dGEMRIC and its validation in vitro and in vivo
- To discuss the advantages and disadvantages of dGEMRIC
- To describe the clinical usefulness of the different GAG specific techniques in osteoarthritis and cartilage repair surgery

Osteoarthritis and cartilage repair - quantitative cartilage imaging
Part 2- proteoglycans – gagCEST
Ch. Rhenitz; Heidelberg/G
- To describe the basic principle of gagCEST and its validation so far.
- To discuss the advantages and disadvantages of gagCEST to other GAG-specific techniques
- To describe the clinical usefulness of gagCEST in cartilage disease and after cartilage repair
Special Focus Session ECR 2015:
Imaging biomarkers in degenerative joint disease

Osteoarthritis and cartilage repair - quantitative imaging of cartilage imaging

Part 3- T2 mapping

GW. Welsch; Erlangen, G
- To describe the different techniques of T2 mapping
- To discuss the advantages and disadvantages of different T2 mapping techniques
- To describe the clinical usefulness of T2 mapping in osteoarthritis and cartilage transplantation

Degenerative joint disease –quantitative imaging of menisci and tendons

T2*, vTE and UTE mapping

V. Juras; Vienna, A
- To describe the basic principle of vTE and UTE and its validation
- To discuss the advantages and disadvantages of vTE and UTE to other T2 mapping techniques
- To report the clinical usefulness of vTE and UTE in menisci and tendon disease

Panel discussion

What are the new imaging biomarkers in degenerative MSK disease?

To discuss which imaging biomarkers are clinically ready as surrogate endpoints and how they can replace arthroscopy with histological evaluation
1. General paradigm shift from qualitative to (semi-)quantitative imaging in radiology generating “imaging biomarkers” => raise the awareness within the radiologic community

2. Definition of possible imaging biomarkers in different human body regions oncologic as well as non-oncologic

3. Identification of variations and errors in quantitative results from imaging methods

4. Development of potential strategies to overcome variations in acquisition and image analysis by hardware, software modifications and protocol optimization

5. Standardization of image acquisition and analysis, implementation of quality assurance measures
6. Due to technical challenges in the different fields modality based Working Groups will be formed (CT/MR/Hybrid-PET/US)

7. **Centers with the respective infrastructure and expertise in biomarker imaging** and having specific cohorts will be identified (co-operation with EIBIR)

8. Close collaboration with QIBA (technical validation synergies) to avoid duplication of development and EORTC (biological validation) to coordinate strategies and to find complementarity

9. **Validated imaging protocols** are disseminated and distributed through vendors, research centers and radiology departments of universities (co-operation with ESMOFIR)

10. Educational activities in biomarker imaging with ESOR courses, Special Focus Sessions at ECR, workshops in the Barcelona learning center and co-operation with ESMOFIR for dissemination and the future development of imaging biomarkers
Thanks for your attention!