Opening and Setting the Scene

Session 1
13:00–14:15
Introduction to the SIMPLERAD project

Bernd J. Krause
The SIMPLERAD consortium

**EIBIR**
Krause, Bernd – scientific coordinator, WP4 lead, WP5 co-lead
Hierath, Monika – project manager, WP5 lead, WP4 co-lead

EIBIR project office
Peld, Nathan D

**EFOMP**
Bardiès, Manuel – WP1 lead, WP3 co-lead
Peters, Steffie – WP2 co-lead
Stokke, Caroline – WP4 co-lead (also EANM)

**EANM Forschungs GmbH**
Herrmann, Ken – WP2 co-lead
Verburg, Frederik – WP3 lead
Gear, Jonathan – WP2 lead
Laßmann, Michael – WP1/3 co-lead
Stokke, Caroline – WP4 co-lead
Covens, Peter
Decristoforo, Clemens
Patt, Marianne
Schulze, Rico – WP1 co-lead

EANM project office
Zieglmeier, Moritz
De Martini, Amélie
Workshop November 2019

Organised by the Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of Experts

RP 194

*Developments in Nuclear Medicine – New Radioisotopes in Use and Associated Challenges*
Main topic

Compliance with article 56 of the BSSD requires treatment planning and verification of the absorbed dose delivered
Issues to be tackled

• Compliance with article 56 of the BSSD requires treatment planning and verification of the absorbed dose delivered
• Lack of European guidance for implementing BSSD, pertaining to the specific difficulties faced in nuclear medicine
• Lack of consideration in EMA guidance regarding marketing authorisation concerning safety of radionuclides
• Confusion between the requirement for optimisation stipulated in the BSSD and the need to follow the posology of the product used for marketing authorisation
• Lack of clarity re. qualitative assessment of delivery verification or a requirement for quantitative analysis based on dosimetry indices
• Lack of medical-physics expertise and physicians’ knowledge on dosimetry in many nuclear medicine centres
• Divergent interpretation within the EU regarding the definition of standardised therapeutic procedures
• Lack of data to make dosimetric comparison for treatment verification
• Lack of guidance for the establishment of appropriate dose constraints
• Lack of harmonisation regarding criteria for patient release from hospitals and management of radioactive waste
• Lack of clarity of the level of optimisation required to comply with European directives on, e.g., patient selection, imaging, dosimetry
Background and challenges addressed

- Therapeutic nuclear medicine and use of radiopharmaceuticals have heralded a paradigm shift towards personalised cancer care
- Crucial to ensure high standards in quality and safety
- Challenges due to a complex and fragmented regulatory framework regarding preparation and use of therapeutic radiopharmaceuticals
  - EU pharmaceutical legislation, currently undergoing revision
  - Euratom radiation protection legislation
- SAMIRA Action Plan provides a welcome framework for the professional community to analyse and address these challenges to ensure high quality of care and safety to Europe’s patients and foster further innovation in the field
SIMPLERAD project attributes

• Timespan: May 2022 – April 2024
• Kickoff meeting with European Commission on 23 May 2022
• Consortium
  • EANM – EANM Forschungs GmbH
  • EFOMP – European Federation of Organisations in Medical Physics
  • EIBIR – European Institute for Biomedical Imaging Research as project management partner
SIMPLERAD general objectives

SIMPLERAD aims to:

• Improve the understanding of the links and interdependencies between the European pharmaceutical legislations and Euratom radiation protection requirements

• Highlight potential barriers to implementation

• Propose practical guidance and recommendations to advance a coherent implementation of these requirements with respect to the therapeutic use of radiopharmaceuticals

• Address quality and safety issues related to the current use and introduction of novel therapeutic radiopharmaceuticals into clinical practice, including requirements for dosimetry, the role of MPEs, release of patients from hospital, and management of radioactive waste
SIMPLERAD specific objectives

• Analyse the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom’s requirements for therapeutic nuclear medicine (WP1)
• Implement a survey on the implementation of the relevant European legal requirements with respect to therapeutic nuclear medicine (WP2)
• Recommend actions to advance the coherent implementation of the European legal requirements with respect to therapeutic nuclear medicine (WP3)
• Organise a project workshop (WP4)
SIMPLERAD Advisory Board

• Strong involvement of stakeholders to ensure high quality project work and acceptance within the communities

• Reviewed deliverables and provided first consultation on draft guidelines/recommendations

• Representatives from relevant international organizations and stakeholders from the UK, as well as regulators, industry stakeholders, patients and other stakeholders not otherwise represented in the project
Work package structure and interrelations

WP1: Analysis of interrelations between EU pharma legislation and BSSD

WP2: Survey on implementation of European legal requirements

WP3: Actions to advance the coherent implementation of European legal requirements

WP4: Project workshop

WP5: Project management, coordination and dissemination
# SIMPLERAD work packages

Co-leads – M. Lassmann, R Schulze |
|---|---|---|
| WP2 – Survey and analysis of the implementation of relevant European legal requirements for therapeutic nuclear medicine | M1-M14 | Lead – J. Gear  
Co-leads – K. Herrmann, S. Peters |
| WP3 – Advancing coherent implementation of European legal requirements for therapeutic nuclear medicine | M4-M24 | Lead – F. Verburg  
Co-leads – M. Lassmann, M. Bardiès |
Co-leads – M. Hierath, C. Stokke |
| WP5 – Project management, coordination, dissemination | M1-M24 | Lead – M. Hierath  
Co-lead – B.J. Krause |
### Project timeline

<table>
<thead>
<tr>
<th>Deliverable numbers in bold</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1 Analysis of the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom</td>
</tr>
<tr>
<td>T1.1 Literature review and further activities</td>
</tr>
<tr>
<td>T1.2 Comparative analysis of the regulatory frameworks in the EU, UK and USA</td>
</tr>
<tr>
<td>T1.3 Report of the analyses and findings of Tasks 1.1 and 1.2</td>
</tr>
<tr>
<td>T2.1 Contact database for questionnaires and expert interviews</td>
</tr>
<tr>
<td>T2.2 Development, implementation and analysis of questionnaires</td>
</tr>
<tr>
<td>T2.3 Design, implementation and summarisation of expert interviews</td>
</tr>
<tr>
<td>T2.4 Summary report, including results of questionnaire replies and expert interviews</td>
</tr>
<tr>
<td>WP2 Survey and analysis of implementation of relevant European legal requirements for therapeutic nuclear medicine</td>
</tr>
<tr>
<td>WP3 Advancing coherent implementation of European legal requirements for therapeutic nuclear medicine</td>
</tr>
<tr>
<td>WP4 Organisation of a European workshop</td>
</tr>
<tr>
<td>WP5 Project management, coordination and dissemination</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>2022</td>
<td>2023</td>
</tr>
</tbody>
</table>

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0