Summary and wrap-up per project task

Bernd J. Krause
Michael Lassmann

Simplerad

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

Challenges to Radiopharmaceutical Therapies - A Broader Perspective

1. Global market share – Europe might be falling behind due to the complexities related to radiopharmaceutical therapies

2. Capacity – lack of capacity of treatment slots due to scarce appropriate infrastructure and workforce

3. Regulations - have massive impact how “attractive and viable” radiopharmaceutical therapies will be vs other treatment options. Radiopharmaceutical therapies have clinically proven to be better for the patients

Simplerad

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

WP1

- In-depth analysis of 7 EU countries and comparison with UK and US clarified legal frameworks, common practices and divergence
- Important missing links among guidance and legislation was highlighted, supporting initial issues to be addressed by the consortium
- Issues needing common standards and explicit guidance submitted to WP3

Simplerad

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

WP2

- Survey collected almost 200 responses with strong representation across Europe, and interviews confirmed and elaborated on common themes
- Legislative issues confirmed the work of WP1 and those in the current practice were highlighted
- Differing criteria and good practices in planning/verification, dosimetry, waste and patient release were important findings submitted to WP3
- Publication and dissemination of results planned after the project is finished

Simplerad

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

WP3

- 10 prioritised issues studied, remedies developed with SWOT analysis of each
- Consultation held with Advisory Board
- Discussion with wider stakeholder community and workshop participants and panellists
- Identified the 5-6 most important topics

Simplerad

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

SIMPLERAD - the 5 most important topics

1. Insufficient linkage between EU pharmaceutical legislation/EMA guidance and BSSD
2. Interpretation and implementation of the BSSD in the context of therapeutic nuclear medicine
3. Differences between opinion of professionals concerning dosimetry and the necessity stipulated in national legislation and guidance
4. Differing regulatory procedures between member states for drug development & clinical trials
5. Sufficient specialist knowledge concerning nuclear medicine within various stakeholders regarding EU pharmaceutical and medicine as well as BSSD-related regulations

AND/OR

5. Lack of resources for dosimetry

These are most important topics that have been discussed over the past 2 days and are the "must"-recommendations of SIMPLERAD

Simplerad

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

WP3

- 10 prioritised issues studied, remedies developed with SWOT analysis of each
- Consultation held with Advisory Board, wider stakeholder community and workshop particpants and panellists
- Identified the 5 most important topics
- Guidelines and recommendations amended based on the results of the consultation process to be finalised and submitted to the EC in final report
- Publication planned

Simplerad

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