Summary of the PRISMAP Education seminar 'Standardization & Harmonization'

8 February 2022 | Online meeting

What is PRISMAP?

Thierry Stora, CERN, Switzerland

PRISMAP the European medical radionuclide programme is a consortium federated by a diverse network of 23 world renown institutions across Europe to advance and secure the applications of novel radionuclides in Europe for cancer care. A robust and stable supply must be made available for the research and development of novel radionuclide applications in radiopharmaceuticals. The projected market shares for radiopharmaceuticals are currently in their growth stage and the promotion of nuclear medicine applications is an important driver to cover the need for innovative streamed lined access to novel radionuclides for the starting research community.

The ambition of PRISMAP is to:

- → Provide access to new radionuclides and new purity grades for medical research
- → Create a common entry port and web interface for the starting research community
- → Enhance clarity and regulatory procedures to promote research with radiopharmaceuticals
- → Unlock the biomedical research through better data on radionuclides
- → Ensure the long-tern sustainability of PRISMAP

Progress in the harmonization and standardization of an emerging infrastructure within this project provides more coherent procedures and regulations to follow for research and development of novel radionuclides for biomedical research. The technical aspects of novel radionuclide production and delivery are provided by world-renowned high energy physics institutions within Europe with access to nuclear reactors, cyclotrons, SINQ and spallation technology. In particular, the addition of mass separation provides new possibilities to produce radionuclides with high specific activity and brings in novel opportunities for imaging and therapy of targeted diseases. This is complemented by the support of research towards the development of novel chelators, new targeting vectors including peptides with targeted biological applications in radiotheranostics.

PRISMAP offers open calls for user projects to the public twice a year; all are encouraged to apply and submit competitive research proposals that will be evaluated and selected. The resulting research findings will be published and advertised publicly in the EU.

Please join the PRISMAP User Forum to keep up to date regarding all of our activities and events: https://www.prismap.eu/radionuclides/user-forum/

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Novel Radionuclides and their Production

Mikael Jensen and Clive Naidoo, Denmark Technical University, and Férid Haddad, ARRONAX, France

A brief historical overview of the medical radionuclides that has been produced on a routine commercial basis since the 1970's is discussed. Categorization of cyclotron (neutron deficient) and reactor (neutron rich) produced radionuclides and the further categorization of SPECT, PET and Alpha emitting radionuclides together with their varying production routes and clinical applications are highlighted. It is shown with the emerging medical radionuclides such as ^{64}Cu, ^{67}Cu, ^{117m}Sn and the alpha emitting ^{211}At and ^{225}Ac the importance of selecting the optimal nuclear reaction for an efficient production of the radionuclide of interest with a high specific activity. The avoidance of potential pitfalls in production also is highlighted. Emerging therapeutic radionuclide production techniques with alpha beams (97Ru), spallation reactions (^{107}Pd), mass separation (^{155}Tb and ^{169}Er), photonuclear reactions (^{47}Sc) and secondary neutron source reactions (^{166}Ho nanoparticles) are also discussed.

An Overview of Radiopharmaceutical Regulations in the European Union

Clemens Decristoforo, Medical University Innsbruck, Austria

Clemens Decristoforo provides an overview of the Pharmaceutical Regulations in the European Union. Starting with the general pharmaceutical regulatory environment in Europe; his talk describes the roles of the European Commission, the European Medicines Agency (EMA) and the EU Member States National Medicines Agencies. As well as relevant players outside the EU, such as the Council of Europe which is responsible for the European Pharmacopoeia. The main Directives and Regulations are described, thereby with a focus covering Directive 2001/83/EC (the "pharmaceutical Directive") with its definitions and relations to radiopharmaceuticals. The regulations on Marketing Authorizations of Medicinal Products and on Good Manufacturing Practices (GMP) are addressed. Quality definitions in the European Pharmacopoeia relevant to radionuclides and radiopharmaceuticals are covered and other guidelines related to the quality of pharmaceuticals addressed. The presentation continues with the EU legislation and guidelines on clinical trials. The new Regulation EU No 536/2014 has recently changed the application process. Finally requirements and guidelines for non-clinical testing of radiopharmaceuticals are presented. Overall the presentation summarized the pillars of the regulatory framework for medicinal products in Europe and indicated major specific legislation and guidance documents for radiopharmaceuticals.

Development of Theranostic Radiopharmaceuticals

Eleni Gourni, University Hospital Bern, Switzerland

Eleni Gourni explains, that radiotheranostics refer to radiopharmaceuticals with the potential to be used for both therapeutic and diagnostic applications in nuclear medicine. This implies that the same targeting vector is suitable to be labeled with two different radionuclides maintaining similar biological and chemical features, whereby one is used for therapy, the second for imaging purposes.The pioneering cocktail, iodine radionuclides for the management of patients with thyroid cancer has been used for several decades in routine clinical applications. More recently, the involvement of radiometal-based radiopharmaceuticals into the theranostic concept has been proven to be more advantageous. Thus, the interest relies on two major parameters: firstly, the increasing availability of new radionuclides that full fill the prerequisites for the development of radiotheranostic `twins` within the frame of their true concept (the therapeutic and the diagnostic are radionuclides of the same element). Secondly, the continuous development of valuable radioligands for the management of cancers; such as prostate and neuroendocrine tumors have contributed to the growth of radiotheranostics. This talk provides an overview about recent developments and the necessary steps involved. It describes the personalized approach including dosimetry of radiotheranostics in patient management of cancer care.