PRISMAP Survey
Radionuclide and Radiopharmaceutical Industrial and clinical collaboration

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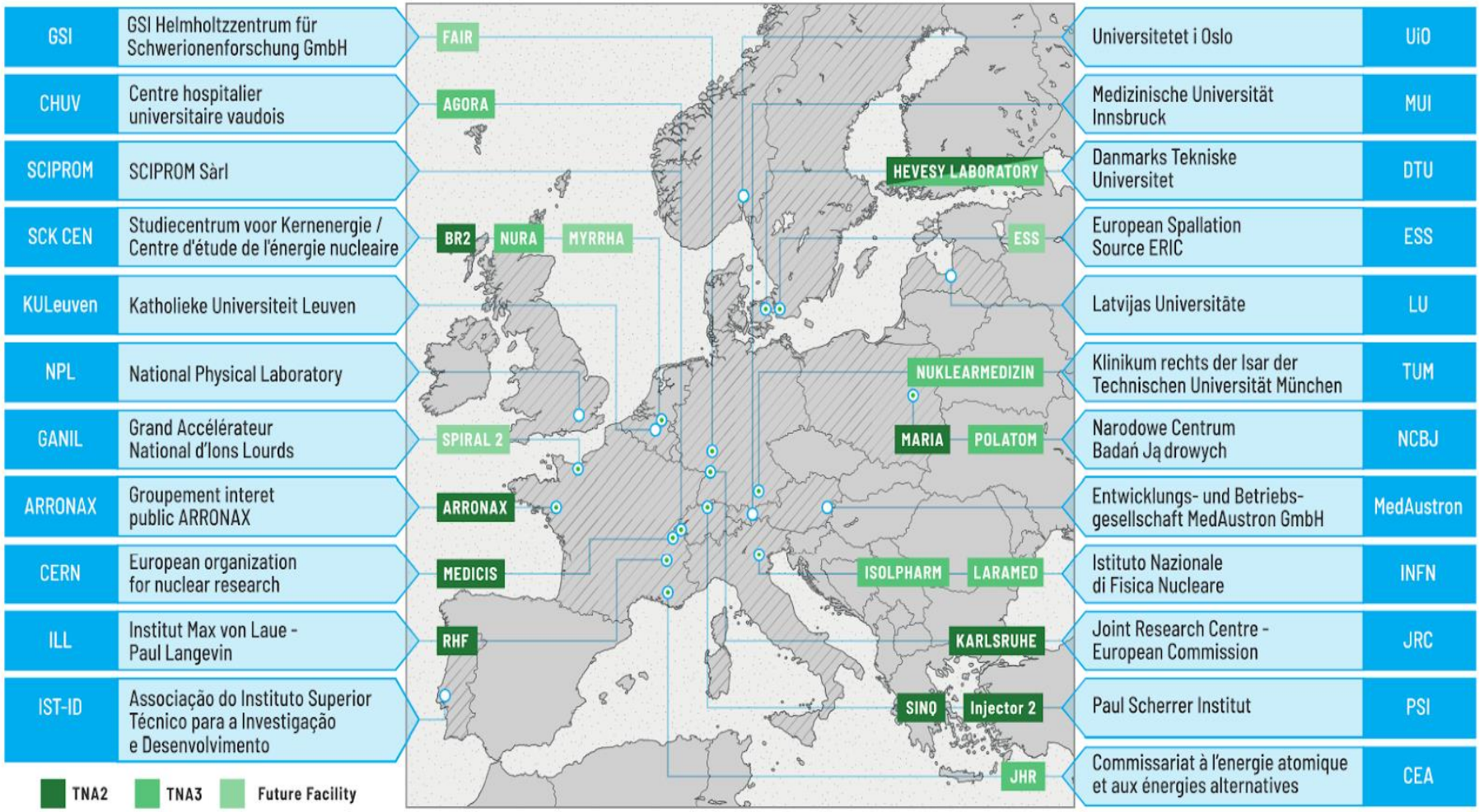
11.10.2022



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PRISMAP PROJECT

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101008571 (PRISMAP).

NETWORKING – dependencies on other WPs

From the Survey responses we can confirm the necessity of PRISMAP

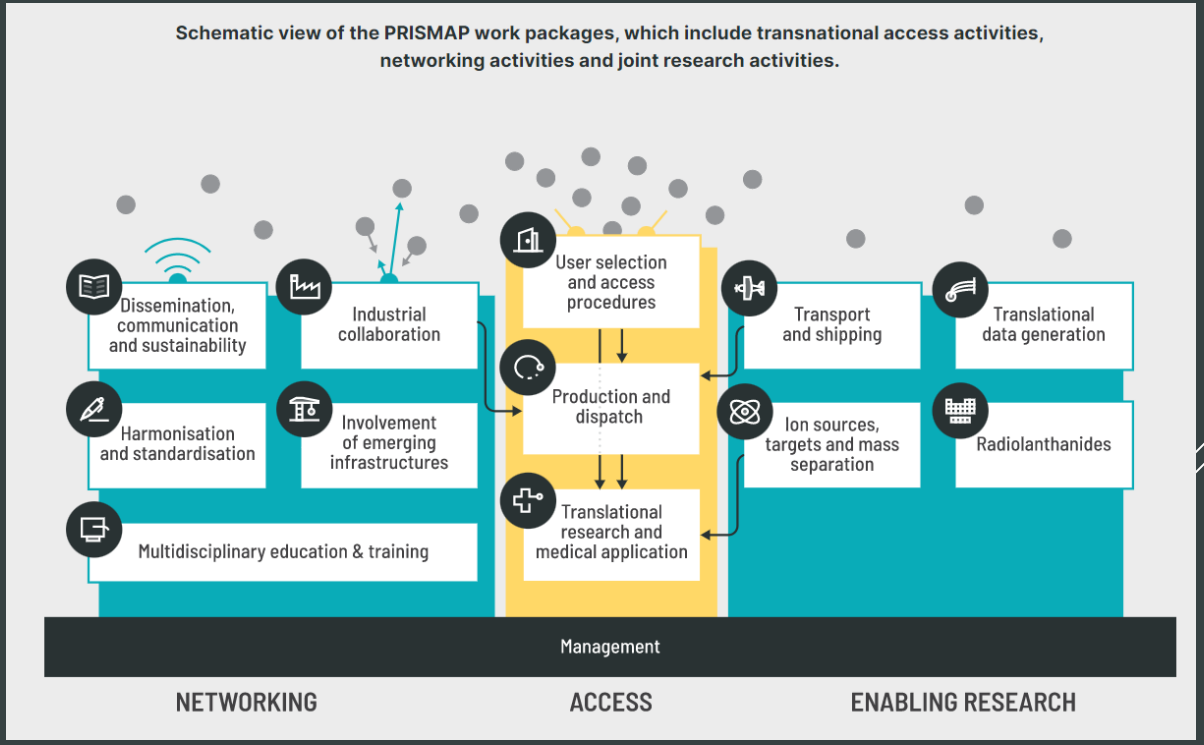
not only as a web-based entry platform for the production and dispatch of non-conventional radionuclides, but also as a long-term platform for aiding an advancement in, at the moment, emerging radionuclide distribution and use in research and nuclear medicine

Excellent collaboration with :

ILL, DTU, KULeuven, CERN, SCIPROM, MUI, PSI

For survey design, responses, target groups etc.

New research and industry contacts needed!



What are the objectives for WP5?

WP5-NA2
Industrial and clinical collaboration

WP5-NA2 will set links with clinical and industrial research communities to promote the services of PRISMAP and integrate the specific needs of these researchers. The information collected and generated will be used to evolve the PRISMAP common interface WP1-TNA1 and it will naturally interface with WP2-TNA2 and WP3-TNA3 services to evolve the services to meet the industrial and clinical researcher needs.

- **WP5-NA2 strives to foster the industrial and clinical collaboration, identifying the needs of industrial and clinical end-users to enrich and adapt the PRISMAP product and service portfolio accordingly**

NETWORKING

- Universities
- University hospitals
- Reasearch Laboratories, Institutes – radiopharma, radiochemistry, radiophysics
- International professional organizations (EANM, ESR, ESHI etc.)
- International authorities - IAEA, NuPECC etc.
- Industrial authorities (NMEU, EFPIA, IBA etc.)
  - Reactor, Cyclotron manufacturers
  - Radiopharmaceutical companies
  - Detector manufacturers
- End users – nuclear medicine, molecular imaging and radioisotope specialists, researchers, students

NuPECC
Nuclear Physics European Collaboration Committee

IAEA
International Atomic Energy Agency

ESR EUROPEAN SOCIETY OF RADIOLOGY

NUCLEAR MEDICINE EUROPE

efpia
European Federation of Pharmaceutical Industries and Associations

EANM
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE

iba RADIO PHARMA SOLUTIONS

IFPMA
International Federation of Pharmaceutical Manufacturers & Associations

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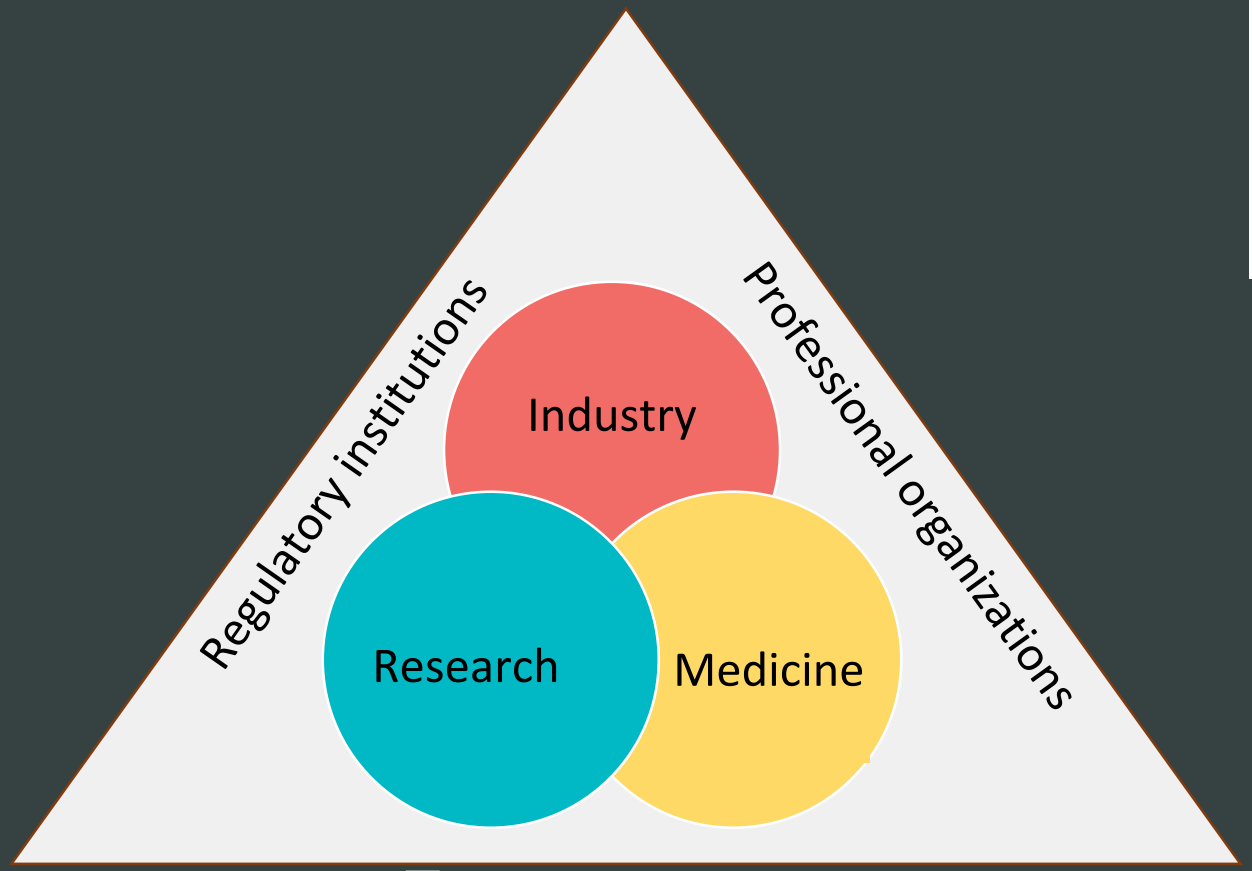
Team within PRISMAP - LU





- **Assoc. Prof. Maija Radzina**, Radiologist, President of Latvian Radiology Association (NM included)
- **PhD student Edgars Mamis**, MSc in Chemistry, experience in RN cyclotrone production
- **Assoc. Prof. Elina Pajuste**, Institute of Chemical Physics, Chief of Radiochemistry lab
- **Dr. Laura Saule,** Paula Stradina clinical university hospital, Radiology resident
- **Dr. Marika Kalnina,** Paula Stradina clinical university hospital, Radiologist, Nuclear Medicine specialist, National representatie at EANM

SURVEY GENERAL CONCEPT



Foster the industrial and clinical **collaboration**, **identifying the needs** of industrial and clinical end-users to enrich and adapt the product and service portfolio accordingly

Goal of the surveys is to identify industrial, research and clinical partners and their:

- Geographical location (for the map)
- Capabilities (infrastructure, current profile, competences, licensing and other relevant matters)
- Further vision (R&D activities, overall goals)
- Needs to achieve the goals (including interaction with other target groups, education)

TASK NO1 = SURVEY (M6-M12)

- Identify key players in the industrial and clinical communities in the context of PRISMAP and investigate the needs of industrial and clinical end users
- Source, availability, limitations, registration, licence, developments, necessity, future perspectives, confidentiality NDA, education
- WP1, WP2, WP3 - CERN, SCIPROM, KULeuven, PSI, ARRONAX, ILL etc.

OVERALL STRUCTURE OF THE SURVEY

Aim of the overall project
Aim of particular survey,
Link to the Prismap web page

General information
- **Name**
- **Address**
- **Type**
- **Size**
- **etc**

Profile
- **Infrastructure**
- **Competences**
- **etc**

Vision
- **Growth**
- **Directions**
- **R&D**
- **etc**

Needs
- **Related to the interaction with other groups, education**

Possiblity to leave a comment and an a chekcbox if interested to receive further information related to the survey and its results

Confidentiality was assured to the responder, respected and included in the structure of the survey

27 EU PRISMAP Medical Radionuclides

SURVEY FOR NUCLEAR AND PHARMA INDUSTRY

Target - Head of Production, Quality, R&D director, secretaries
Profile - hot cells, accelerators, reactors, cyclotrone, RN generators, synthesis modules, QC equipment, RFP precursors, purity, availability,GMP, GDP (manufacturing and distribution), licences, sterility
Vision - extension of portfolio,registration, QC, novel production
Needs - labeling, targets, logistics

Radionuclide producers

Radionuclide and/or radiopharmaceutical producers

SURVEY FOR SCIENCE & RESEARCH

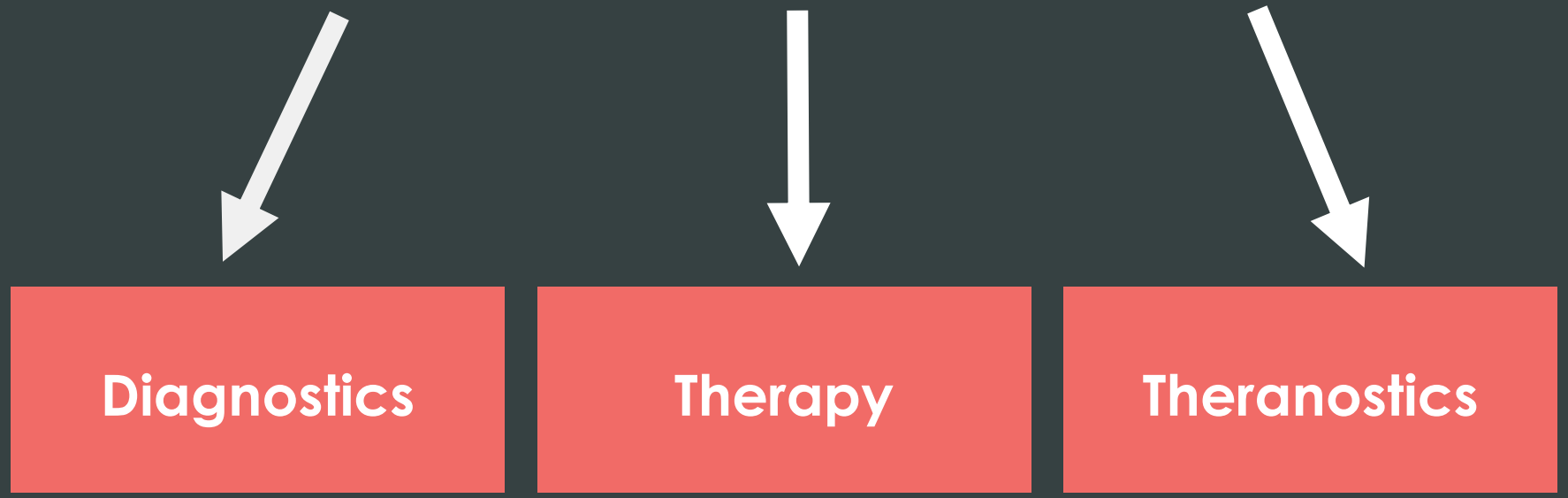
Target audience - Leading researchers, institute directors
Profile - Infrastructure, irradiation source, unique know-how, main radionuclides, pre-clinical, clinical
Needs - supply, projects, human resources
Vision - 5-10 years, expand research, new drugs, plans for infrastructure

Small research facility

Large research facility

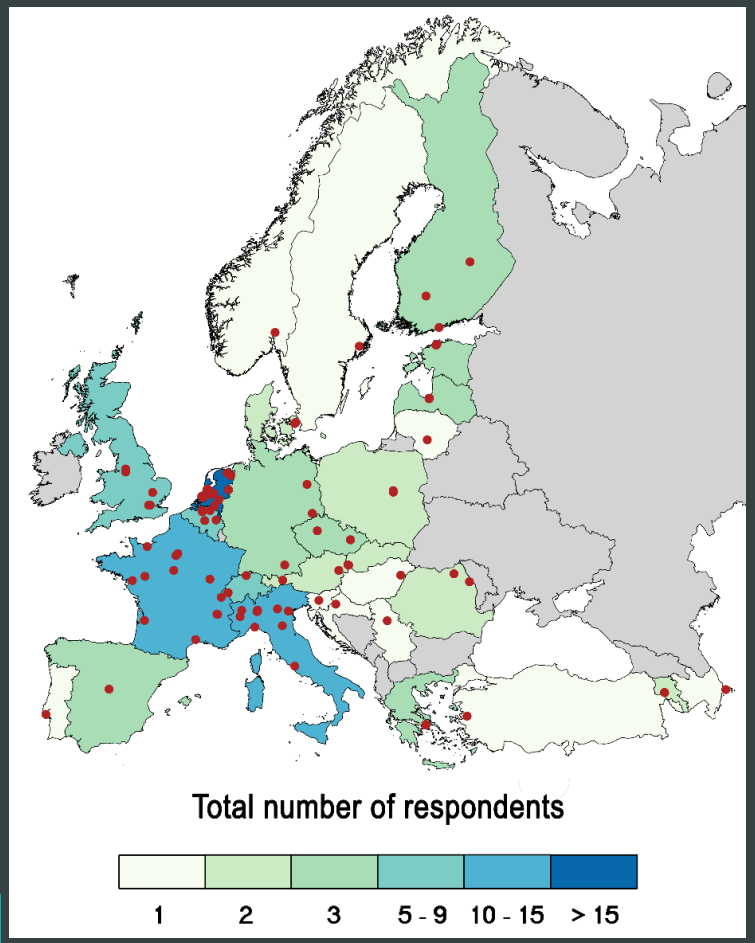
SURVEY FOR NUCLEAR MEDICINE

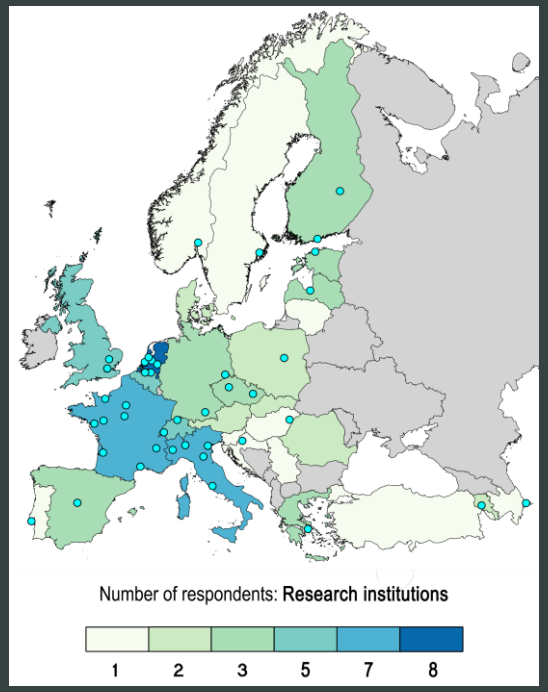
Target audience - Physician, doctor, principal investigators, clinic administration
Profile - clinical, pre-clinical, in-house RP, applications, RN, methods SPECT, PET, etc.
Vision - clinical future perspecives, specialist training, cooperation, supply chains
Needs - access to supplieres, logistics, licences, competences, partners, infrastructure, patient data pooling

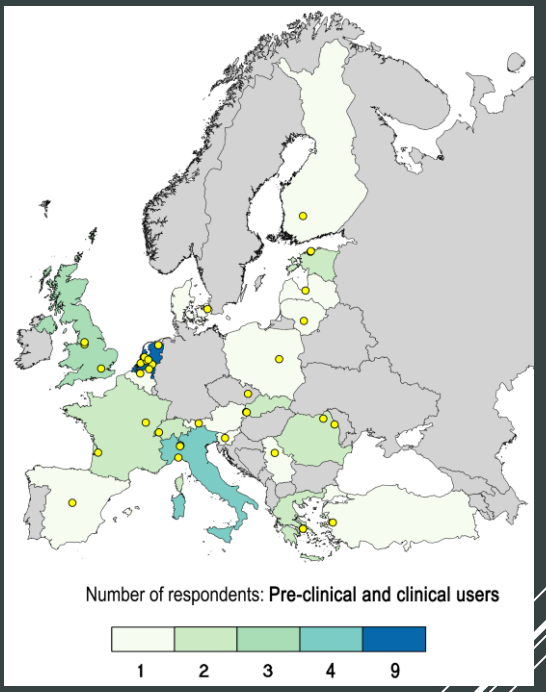


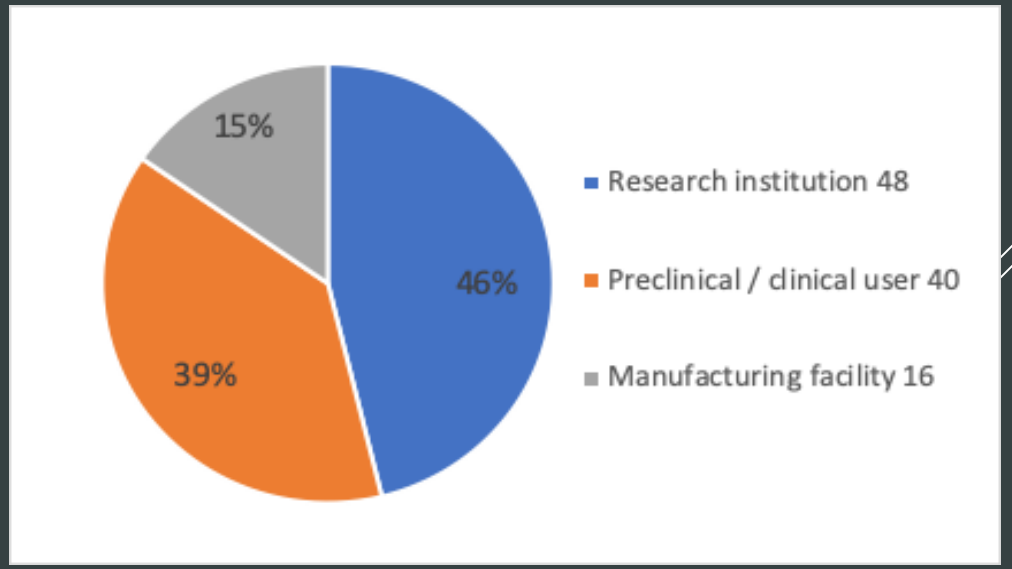
114 respondents from 30 countries

- 104 institution respondents

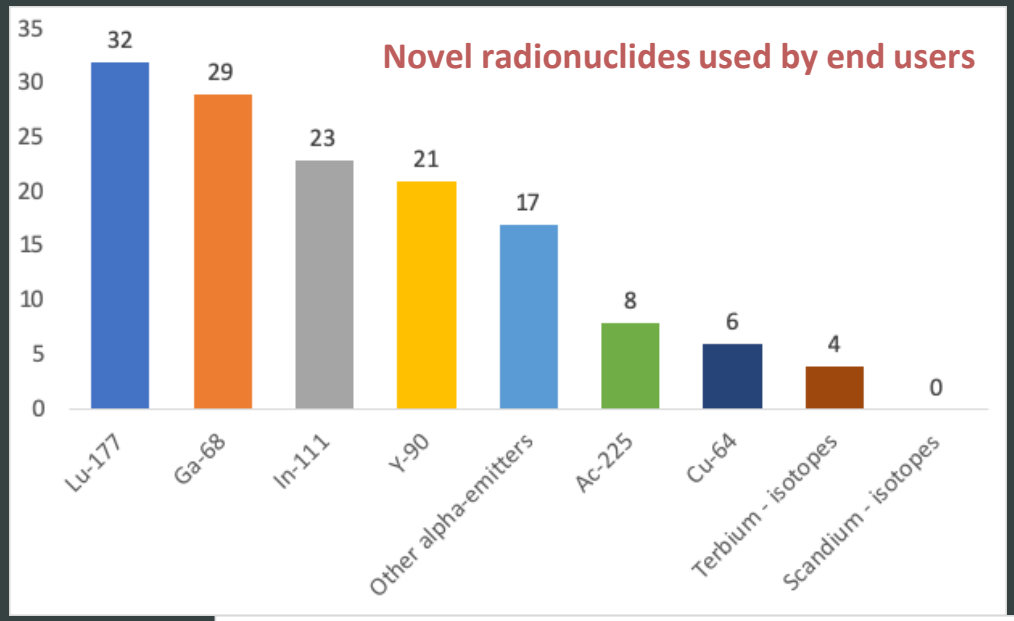


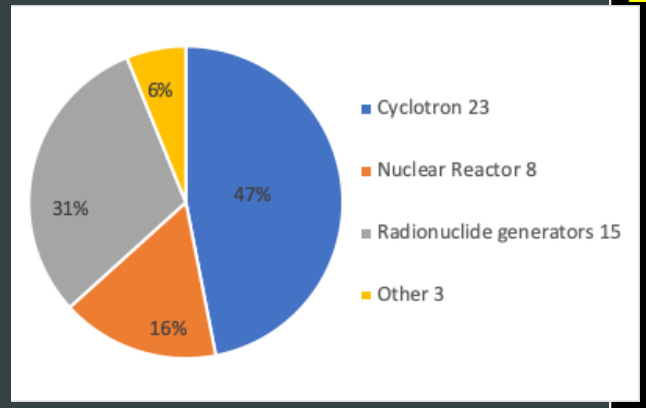


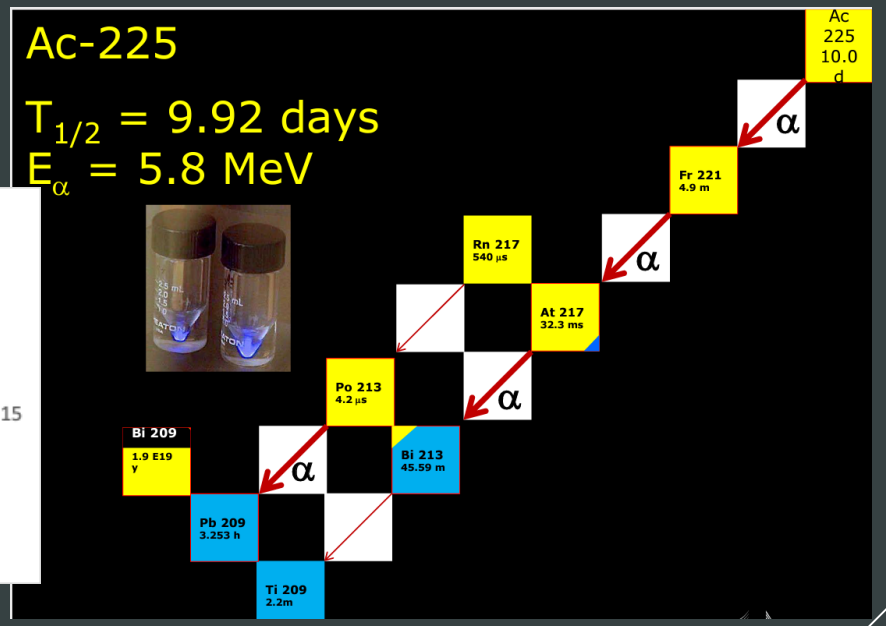


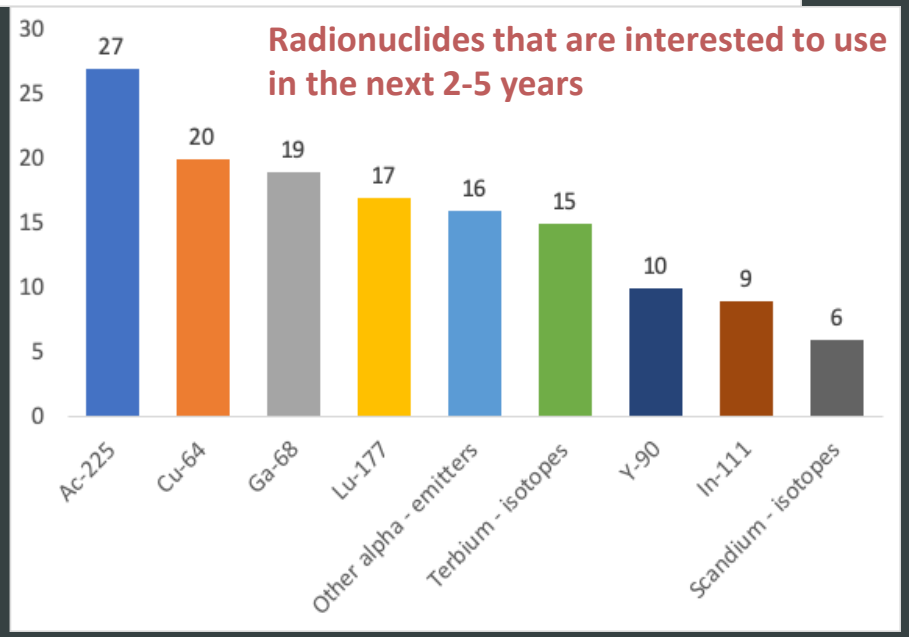


PRODUCTION OF RADIONUCLIDES









- Proven by the end-user questionnaire, recently amongst the research user community there has been an increasing demand for the alpha emitting radionuclide ^{225}Ac, which has been indicated by only one of the production respondents (CERN-MEDICIS)
- The aim to indicate more sites that would offer such increasing demand for radionuclides is still an open objective with high importance

Other:

123I,

124I,

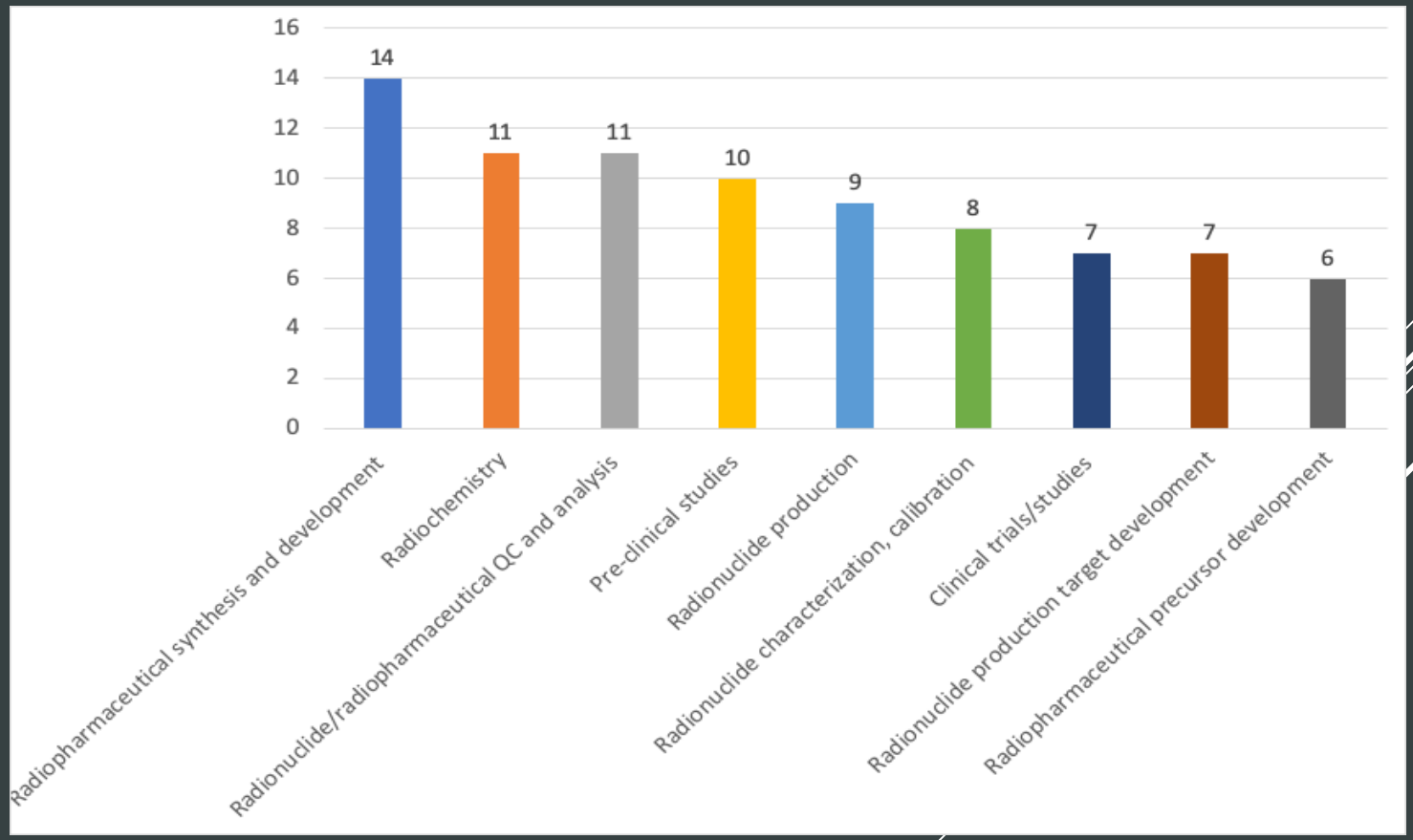
161Tb , 188W, 195mPt, 211At , 225Ac, 135La, 53Mn, 54Mn, 155Tb, 188W,

47Ca/47Sc, 103Pd, 103Ru, 111Ag, 129mXe, 131mXe, 143Pr, 149Pm, 153Sm,

165Er, 128Ba, 155Tb, 212Pb

RESEARCH FIELD AND INTERESTS

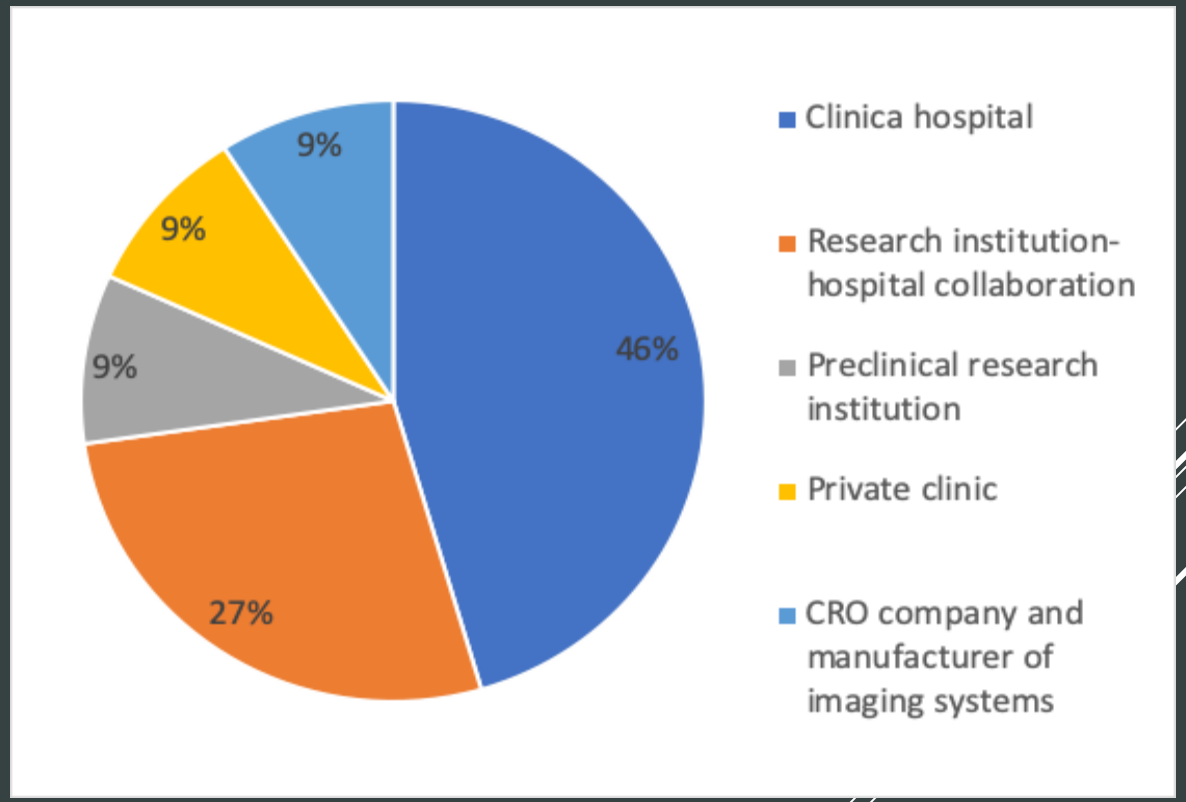
- Animal PET/CT or PET/MR (8)
- PET, PET/CT or PET/MR (7)
- Animal SPECT or SPECT/CT (7)
- SPECT, SPECT/CT or SPECT/MR (5)
- Experimental long term animal facilities after radiation exposure (5)



END USER QUESTIONNAIRE

- **Total 40 respondents**

- All respondents from the nuclear medicine/user section perform studies in oncology, fewer in cardiology, inflammation, endocrinology, neurology, traumatology/orthopaedics, nephrology and pulmonology.
- Necessity to transfer patients to other countries for specified Nuclear Medicine examinations and/or treatment procedures were required in up to 70 % of end user respondents for following reasons - unavailable radiopharmaceutical access, unavailable radionuclide or no reimbursement by the national healthcare system.
- End users are interested not only in new radionuclides and pharmaceuticals for research and preclinical/clinical purposes, but also in technology advancements that shows their interest in development but first of all is responsibility of individual centres and not the purpose of this consortium.
  - oncology
  - cardiology
  - infection and inflammation
  - endocrinology
  - neurology
  - animal PET/CT or PET/MR with experimental long term animal facilities for radionuclide therapy studies



ISSUES WITH THE ENRICHED MATERIAL SUPPLY/STOCK

- Bottleneck for the producers is the availability, which goes hand-in-hand with purity/enrichment grade. Because higher isotopic purity is necessary, the availability decreases drastically

- The results show that ½ responders already have national and international distribution routes and methods established. It would be notable to emphasize longer distance distribution routes, such as EU-USA, IT-NL, FR-DK, CH-PK as they require more logistics issue solving and legislation

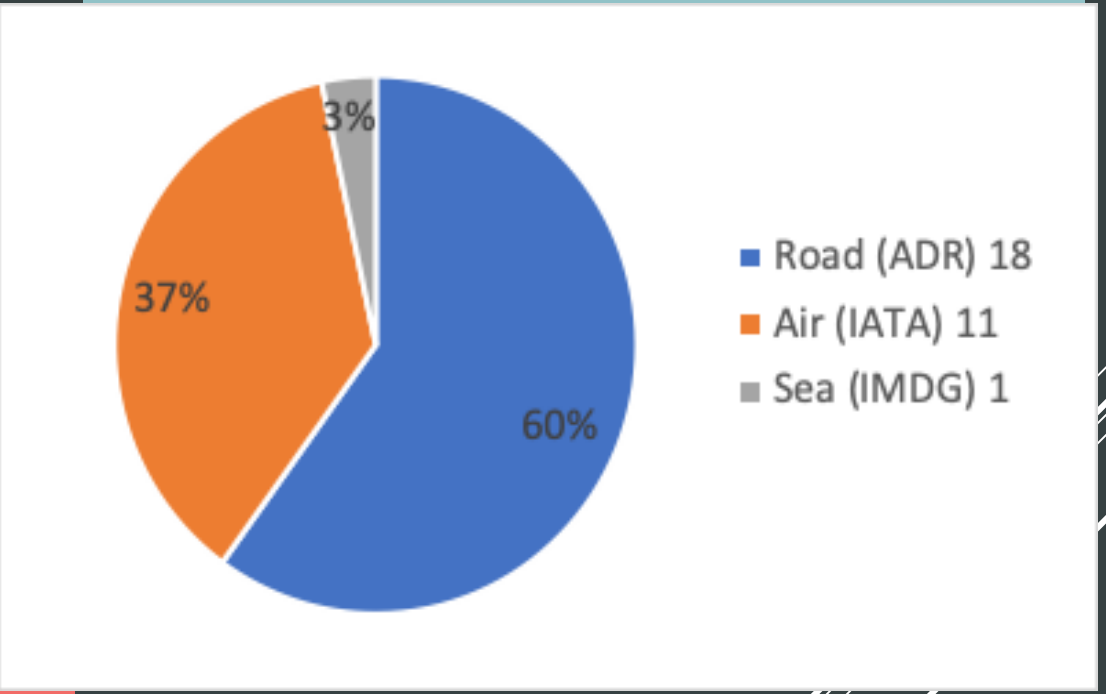
DISTRIBUTION OF RADIONUCLIDES

11/22 institutions plan to increase manufactured volume of radionuclides in following years

Main limitations

- Shortage of staff, expertise
- Infrastructure
- "Beam time" or production capacity
- Target material supply

The most often mentioned external suppliers -



The main limitations or transportation issues that respondents faced

- regulatory limitations
- lack of harmonised import/export legalisation
- complex supply chains
- licensing

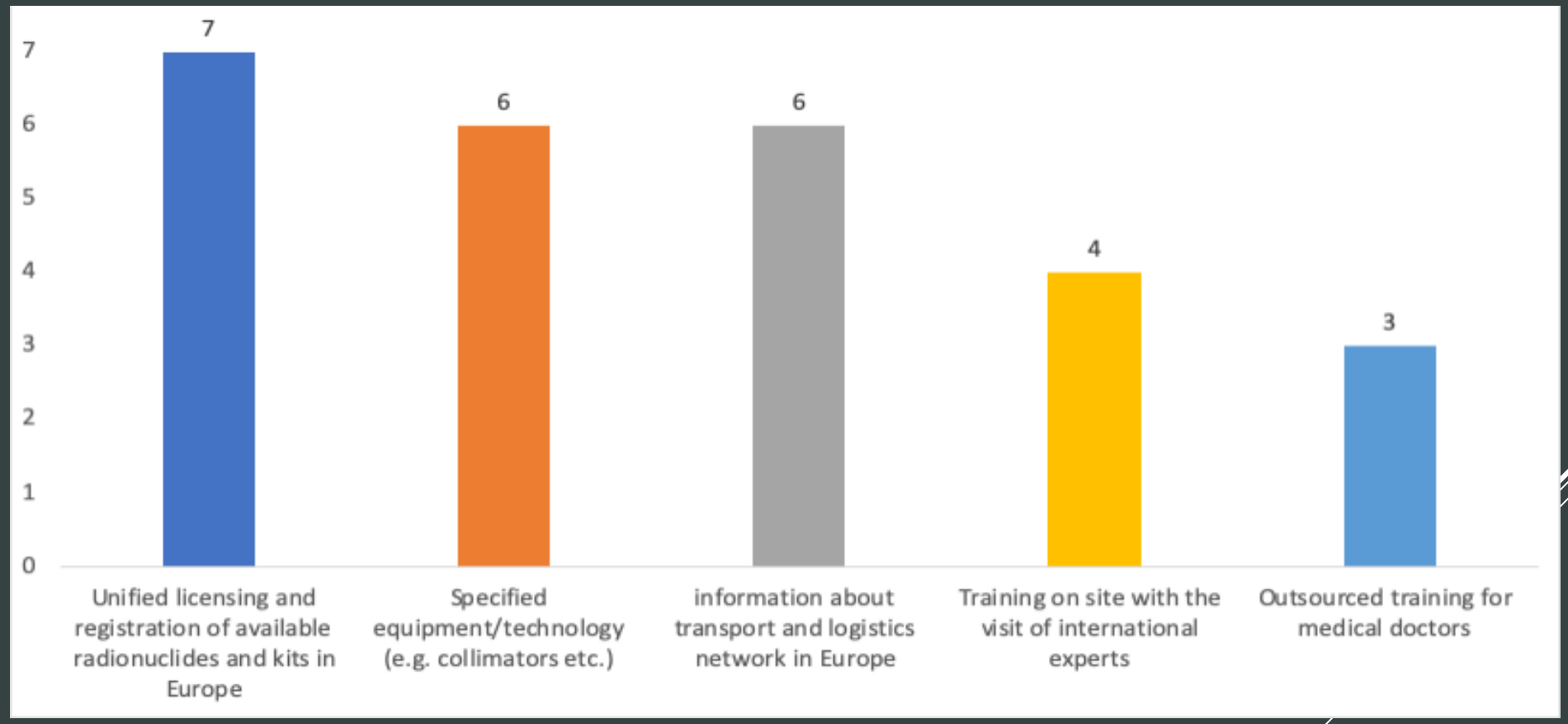
NCBJ (Poland) and CERN-MEDICIS (Switzerland-France) as core PRISMAP consortium members with their expertise and existing distribution routes to a large number of international recipients

LIMITATIONS TO INCREASE MANUFACTURING OF RN

- Main limitations that respondents face or foresee -
  - Shortage of staff, expertise
  - Infrastructure
  - “Beam time” or production capacity
  - Target material supply

Future radionuclides:
149Tb, 152Tb, 155Tb, 149Tb, 161Tb, 225Ac, 89Zr, 67Cu, 64Cu, 165Er/169Er, 47Sc, 44Sc, 177Lu, 211At, 188Re

PRECLINICAL/CLINICAL USERS NEEDS FOR DAILY PRACTICE

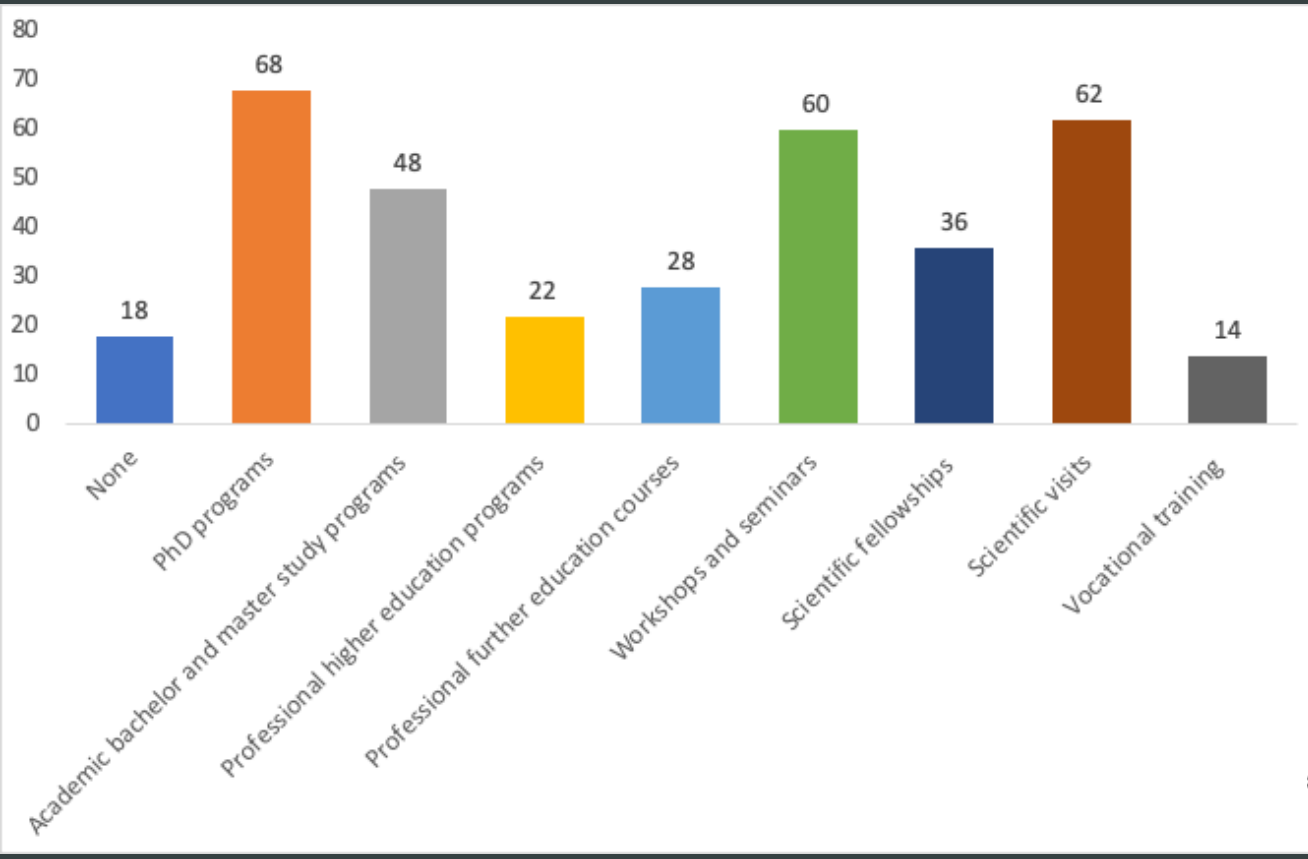


RESEARCH AND DEVELOPMENT ACTIVITIES

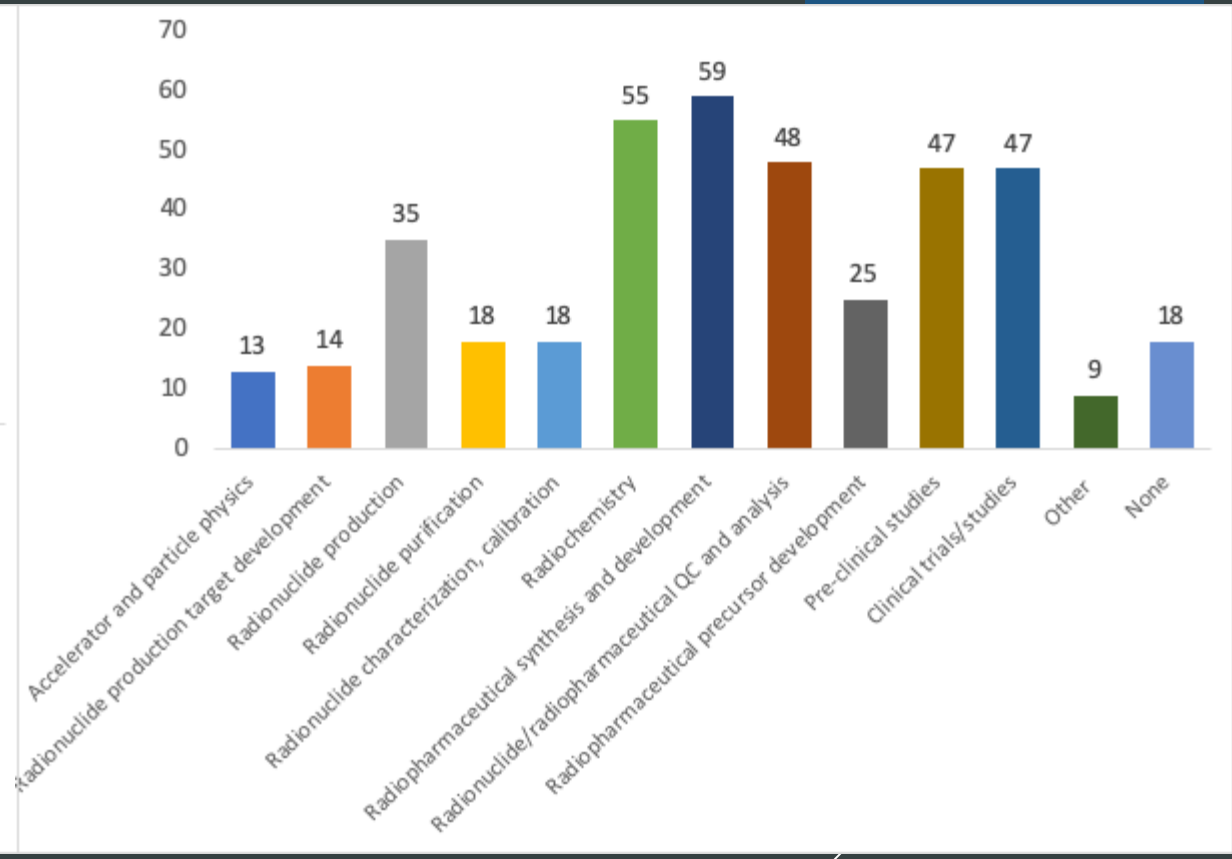
- 83% of respondents indicated that their R&D activities would benefit from collaboration/cooperation, offered by efforts of the PRISMAP consortium

- Main radionuclides of interest are 175Yb,
- Tb radionuclide "family", 67Cu, 64Cu, 43Sc, 44Sc and 47Sc

TRAINING



Types



Fields

LIMITATIONS IN THE TRAINING PROCESS

- Low funding
- Difficulties in recruiting students
- The lack of technical staff
- Lack of integrating radiopharmaceutical research in faculty courses and student curricula
- The number of participants - too low to organise training courses
- Insufficient access to radioisotopes
- No dedicated program for NM physicians, technologists and radiochemists in university
- Lack of trained pre-clinical scientists with a global view from radiochemistry to pharmacology
- Lack of fundamental background knowledge on nuclear physics and research reactors when coming from university

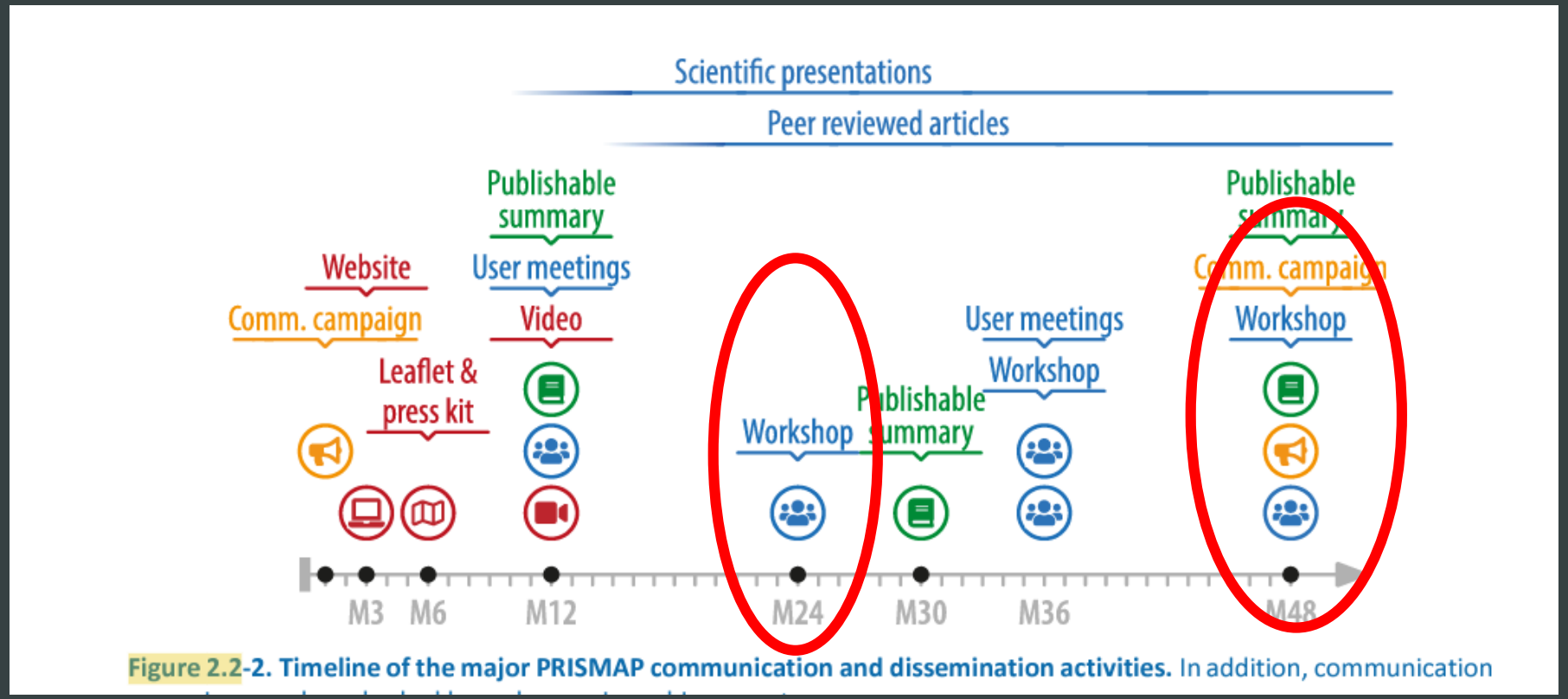


Figure 2.2-2. Timeline of the major PRISMAP communication and dissemination activities. In addition, communication

Two Workshops are organised in WP5-NA2 for the industrial and clinical communities + in WP6-NA3 for training purposes

					Year 1	Year 2	Year 3	Year 4
WP5	**NA2 – Industrial and clinical collaboration**	1	48	48			MS7 MS8	MS10
T5.1	Questionnaire to identify key players and their needs	1	12	12	D5.1			
T5.2	Presentation of the PRISMAP portfolio and networking	6	48	43				D5.2

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PRISMAP

Medical Radionuclides

Networking Activities are expected to fulfil the impact of PRISMAP:

1. We need strong network to achieve our common goals, participating and sharing the information is the key – website, educational and professional activities, social media, industry and political stakeholder involvement

2. Closer interactions between larger number of researchers active in and around a number of infrastructures facilitate cross-disciplinary fertilisations and wider sharing of information, knowledge and technologies across fields and between academia and non- academic stakeholders, including industry.

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