IFIGENEIA

Innovative Facility for Isotope GENeration with Efficient Ion Accelerator

T4.5 Develop protocols for pre-clinical evaluation of ligand-isotope compound

Presenter, GNP

Kick-off meeting
3-4 April 2025
Thessaloniki, Greece

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T4.5 Description

T4.5 Develop protocols for pre-clinical evaluation of ligand-isotope compound

Development of valid pre-clinical evaluation protocols of novel ligand-isotope compounds will significantly **promote their validity and safety during clinical applications**.

The aim of this task is to **develop experimental protocols and related methodologies needed for pre-clinical *in vivo* testing** of produced ligand-isotope compounds.

Measures for the appropriate lab conditions within an **experimental animal facility unit** during isotope and animal handling will be described, to ensure adequate radiation protection and avoid contamination, always following the rules of national legal frameworks.

Also, a **detailed pre-clinical *in vivo* experimental protocol** that will address the safety (including pharmacodynamics and pharmacokinetics), tissue distribution profile, possible diagnostic and prospective therapeutic applications of ligand-isotope compounds, will be developed.

T4.5 Develop protocols for pre-clinical evaluation of ligand-isotope compound

Start Date:	**M19**
End Date:	**M48**

Task Leader:	**Assist. Prof., Bekiari Chryssa**
Task Contributors:	Dr Kosmas Badiavas, Mr George Parathyras, Ms Maria Bigaki, PhD student

Del.	Deliverable Title	Lead Partner	Diss. Level	Due On
D 4.3	Develop protocols for pre-clinical evaluation of ligand-isotope compound	GNP	SENSITIVE	48

Mx	Milestone Title	Lead Partner	Mean of verification	Due On
4.	Pre-clinical protocol finalization	GNP	D 4.3	48

T4.5 Methodology

Develop protocols and methodologies needed for *in vivo* testing of produced ligand-isotope compounds in an experimental animal facility:

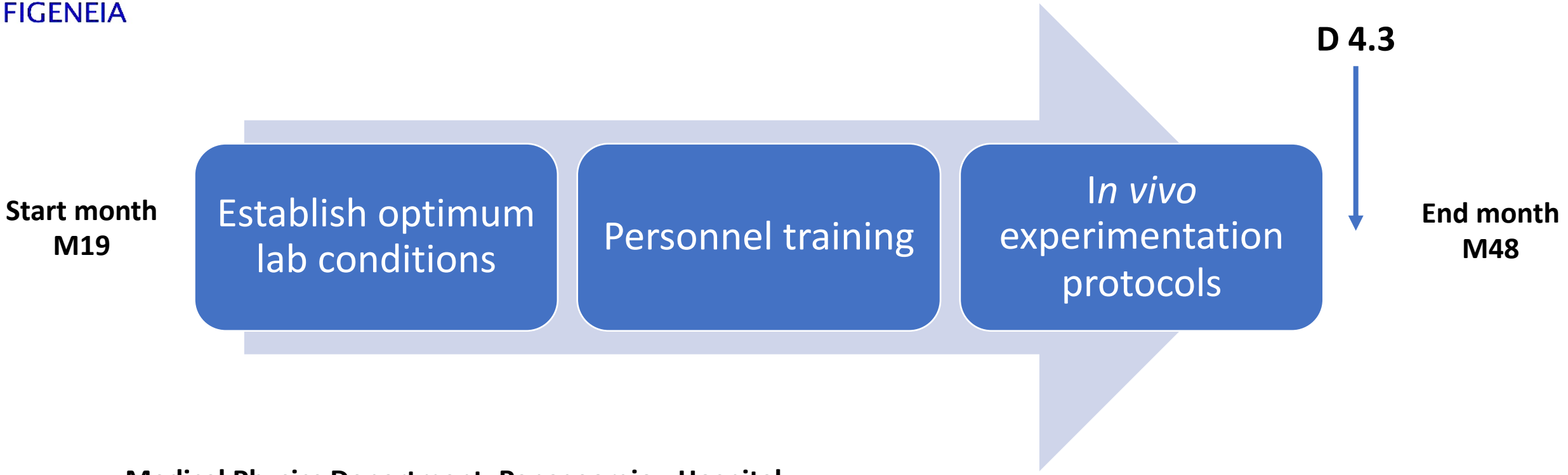
I. Optimum lab conditions during isotope and animal handling (preparation room and animal room shielding, proper equipment).

II. Adequate personnel training (radiation protection, isotope handling, isotope administration to animals, contamination management, waste disposal, animal euthanasia and disposal).

III. Detailed experimental protocol that will be able to evaluate:

- Pharmacodynamics and pharmacokinetics of produced ligand-isotope compounds.
- Tissue distribution profile of produced ligand-isotope compounds via diagnostic imaging studies for tumor visualization (PET or SPECT).
- Prospective therapeutic applications of produced ligand-isotope compounds (predict longitudinal tumor volume changes, survival outcomes and tumor analysis by histopathology and immunohistochemistry ideally in patient-derived xenograft / PDX animal models).

T4.5 Timetable - Resources



- **Medical Physics Department, Papageorgiou Hospital.**
- **Experimental and Research Center, Papageorgiou Hospital.**
- **Program Management Office (PMO), Papageorgiou Hospital.**

Interactions with other Tasks

Other tasks of WP4 – Radioisotope production and radiopharmaceuticals :

- T4.1 Develop Lab conditions (radiation protection) needed for producing these isotopes (M1-M42) [Leader: BIOKOSMOS].
- T4.2 Identify best Isotopes for production with LINAC (M5-M42) [Leader: UL].
- T4.3 Investigate best Ligands for development within excellence hub (M5-M42) [Leader: UL].
- T4.4 Perform the development and testing of ligand-isotope compound (M5-M42) [Leader: DKFZ].

Optimum lab conditions for handling of ligand-isotope compounds.

Ligand-isotope development.

Production of ligand-isotope compounds and *in vitro* testing.