

Implementation of a Outsourcing activity for radiopharmaceutical preparation

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Introduction

Need to develop a **gallium-68** (⁶⁸Ga) radiopharmaceutical **preparation** activity

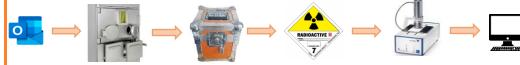
But a main economical obstacle because:

- Limited patient cohort
- Substantial expenses of germanium-68/68Ga generators and cold kits
- Implementation in 2019 of an **centralized production** with **outsourcing** (OS) of these preparations to other hospitals
- Some specific constraints to handle: radiopharmaceutical preparations are subject to both drug and radionuclide regulations, short half-life of ⁶⁸Ga (68 minutes)

OBJECTIVE: Presentation of the necessary steps for the implementation of an OS of radiopharmaceutical preparations and feedback on this activity

Method

Conduction of an practical feasibility study
 → Definition of the pharmaceutical process



Orders

Preparation

Packaging

Shipping

Quality control

Release

2 Requests for authorizations to national agencies



Implementation of a quality management system

- authorization for radiopharmaceutical preparation distribution
- authorization for the possession 4 and use of ⁶⁸Ga
- authorization for the distribution of ⁶⁸Ga
- 4 Redaction and signature of the contracts with partners

Results Evolution of the gallium-68 activity - Outsourcing (OS) 250 200 Somakit - Nb of kit 150 PSMA - Nb of preparation 100 Somakit - Nb of patient 50 PSMA - Nb of patient 2020 2021 2022 2023 Evolution of the gallium-68 activity- Institut Curie 150 Saint Cloud (IC) 125 Somakit - Nh of kit 100 Somakit - Nb of patient 2020 2021 2022 2023

2019 : **3** partner hospitals et **1** Radiopharmaceutical preparation (Somakit®)

2023: 6 partner hospitals et 2 Radiopharmaceutical preparations (Somakit®, PSMA-11)

Better optimization of kits in relation to the number of patients: example of Somakit®

- ✓ In 2019:
 - 1,3 patient/kit for the OS
 - 2,2 patients/kit for IC
- ✓ In 2023:
 - 1,5 patient/kit for the OS
 - 2,7 patients/kit for IC

Discussion

Outsourcing of radiopharmaceuticals preparation: is an INNOVATIVE solution

- → deployment of the ⁶⁸Ga activity in multiple nuclear medicine departments
- → sharing costs
- centralizing expertise

1 critical parameter: Time
 → Requirement of a perfect synchronization between the supplying institution, the transporter, and the receiving institution.

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