

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

- 1 Conduction of a **practical feasibility study**
→ Definition of the **pharmaceutical process**



- 2 Requests for authorizations to national agencies

- 3 Implementation of a quality management system

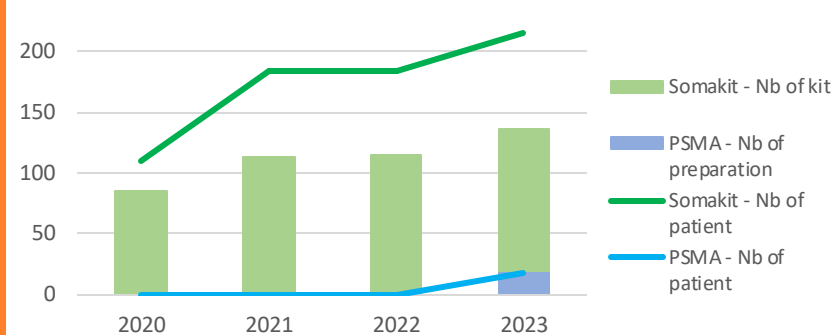


- authorization for radiopharmaceutical preparation distribution
- authorization for the possession and use of ⁶⁸Ga
- authorization for the distribution of ⁶⁸Ga

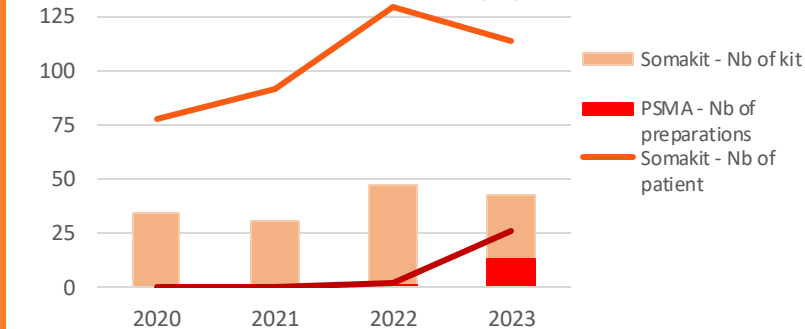
- 4 Redaction and signature of the contracts with partners

Results

Evolution of the gallium-68 activity - **Outsourcing (OS)**



Evolution of the gallium-68 activity - **Institut Curie Saint Cloud (IC)**



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.