

# IMPLEMENTATION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) RECONSTITUTION IN A UNIVERSITY TEACHING HOSPITAL IN FRANCE : PROPOSAL OF A DECISION-MAKING ALGORITHM

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## Background and Importance

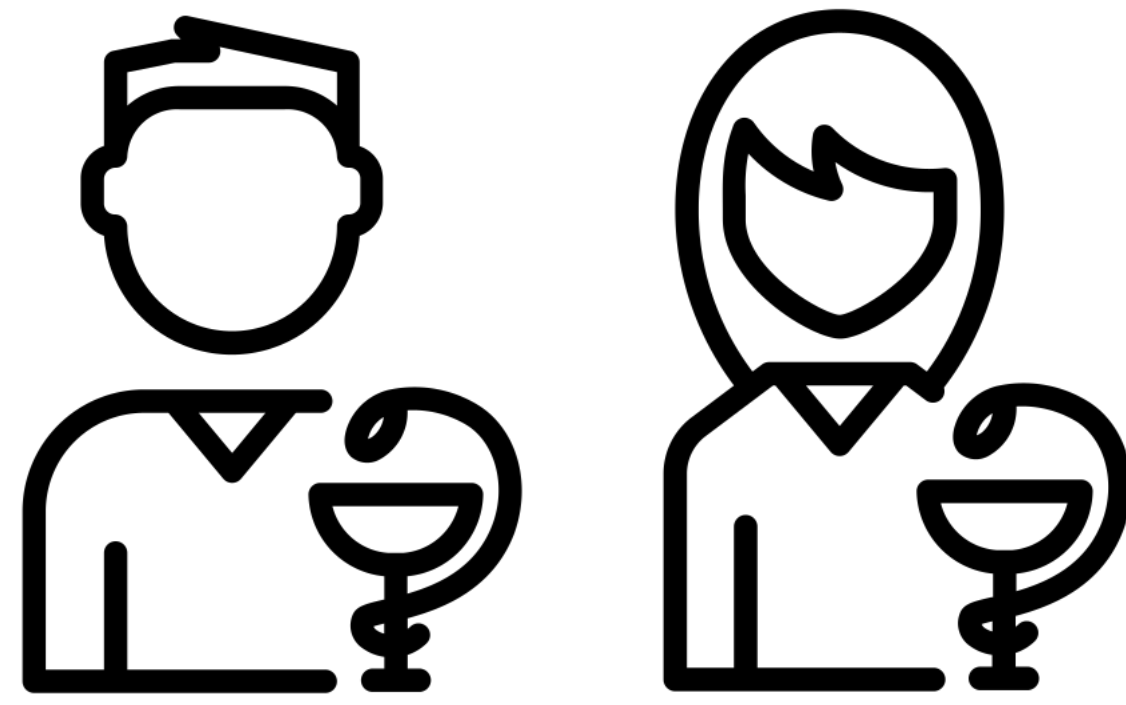
ATMP (genetically modified organisms (GMO) ones or not), use is rising in oncology, requires establishment of a specific organization to ensure a safety circuit.

## Aim and objectives

To implement ATMPs reconstitution in our institution, we built a decisional algorithm for risk and feasibility assessment for each ATMPs.

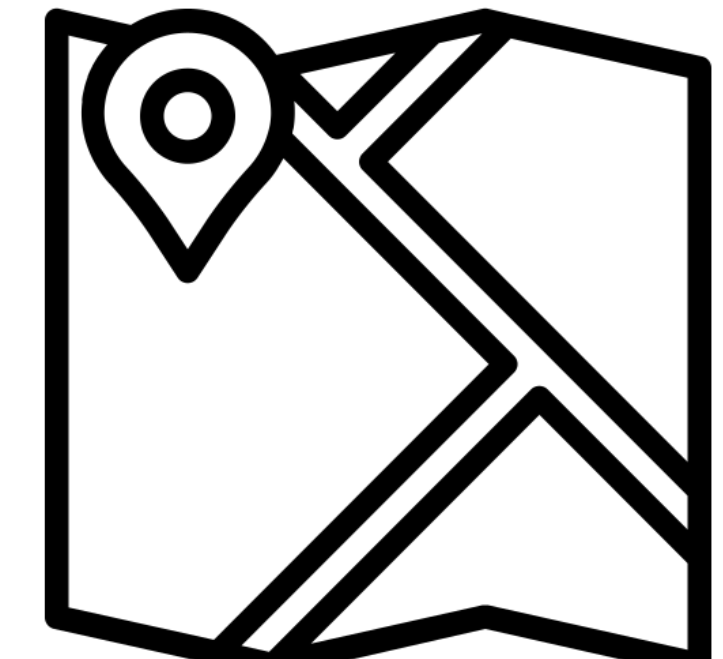
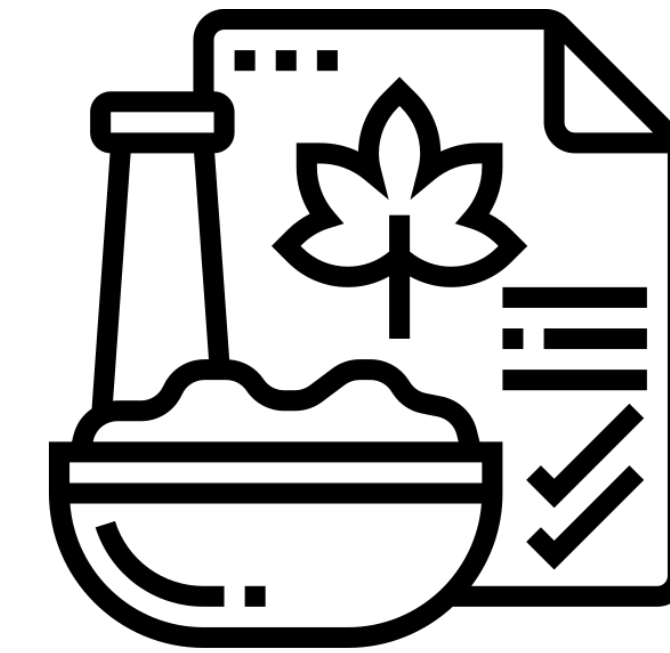
## Material and methods

7 oncology pharmacists



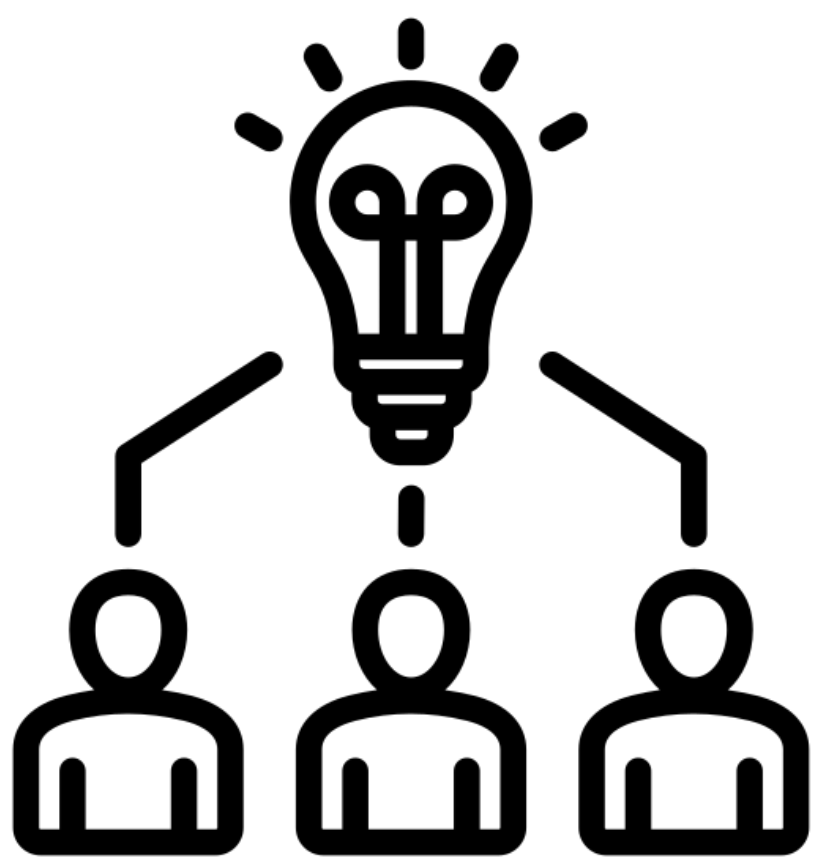
Several competencies

Regulation & Professional guidelines & Organization of our institution



Criticals points were retained

3 brainstorming sessions



A decision-making algorithm based on a yes/no dichotomy progression was built  
Validated with circuit of ATMPs in clinical trials (CT) ever conducted

## Results

6 steps

- o ATMP Nature
- o Storage conditions
- o Thawing conditions
- o Preparation of a not-GMO ATMP
- o Preparation of a GMO-ATMP
- o Waste disposal

34 questions

If a step fails, ATMP can't be used

### STEP 1: ATMP Nature

Point 1: Is ATPM a GMO?	YES	Go to step 1, point 2 ☞
	NO	Go to step 2 ☞
Point 2: Is ATPM classified as containment level 1 GMO?	YES	Go to step 2 ☞
	NO	Go to step 1, point 3 ☞
Point 3: Is ATPM classified as containment level 2 GMO?	YES	Go to step 2 ☞
	NO	ATMP is classified as containment level 3 or 4 and can't be used. ☞

## Conclusion and relevance

This tool was used prospectively to implement tisagenlecleucel, onasemnogene abeparvovec and soon betibéglogene autotemcel in our center.

Furthermore, French Regional Health Agency identified it as a key point to securize our ATMPs circuit

Retrospective scrutiny of our algorithm with ATMPs circuits ever conducted in clinical trials :

- talimogene laherparepvec
- axicabtagene ciloleucel

It appeared to meet all our needs

