

# RISK ANALYSIS OF ADVANCED THERAPY MEDICAL PRODUCTS (ATMPs) CIRCUITS WITHIN A UNIVERSITY HOSPITAL



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Abstract n° : 5PSQ-111

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## CONTEXT AND IMPORTANCE

Diversity of ATMPs + their high cost + their regulatory requirements = Establishment of complex pharmaceutical circuits

In our local organization,

Collaboration with many partners



Risk of errors INCREASE

Multisite



Large number of people involved



## AIM AND OBJECTIVES

- Map and analyze all risks to our ATMP circuits
- Propose corrective and preventive actions (CAPAs) for unacceptable risks

## RESULTS

### Multidisciplinary working group creation

→ 15 participants including 8 pharmacists  
Average experience in ATMP's field : 3.6 years

→ 7 steps identified in our processes = 7 working groups

Prescription

Reception from supplier

Reconstitution

Traceability and finance

Administration

Intra hospital logistic

Professional and environmental risks

→ 16 working sessions

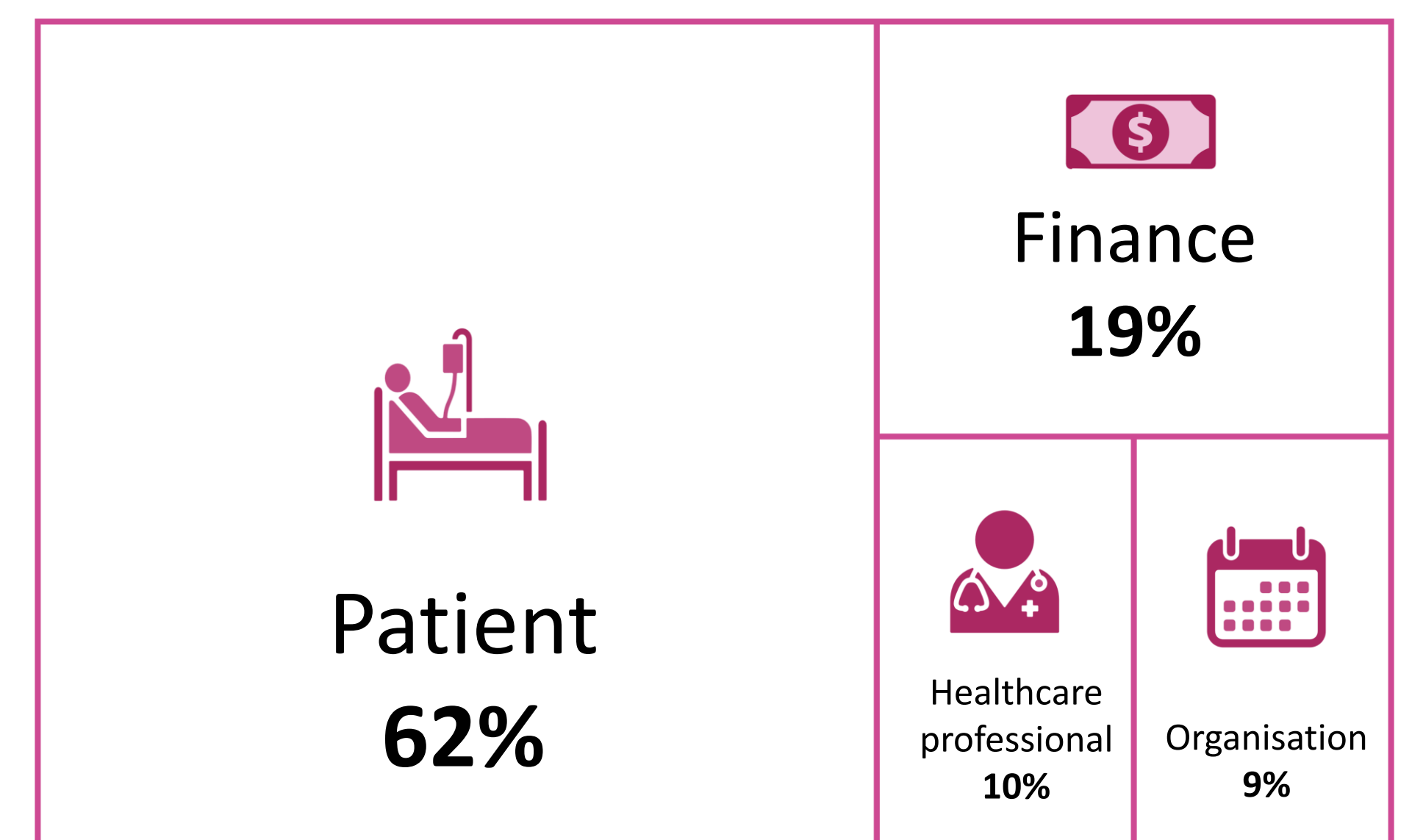
### Scoring and criticality measurement of each risk

Unacceptable risks 14 %

→ The most critical step = RECONSTITUTION

→ Unacceptable risks affect ...

Acceptable risks 86 %



WORKING GROUP

THE RISKS

CRITICALITY

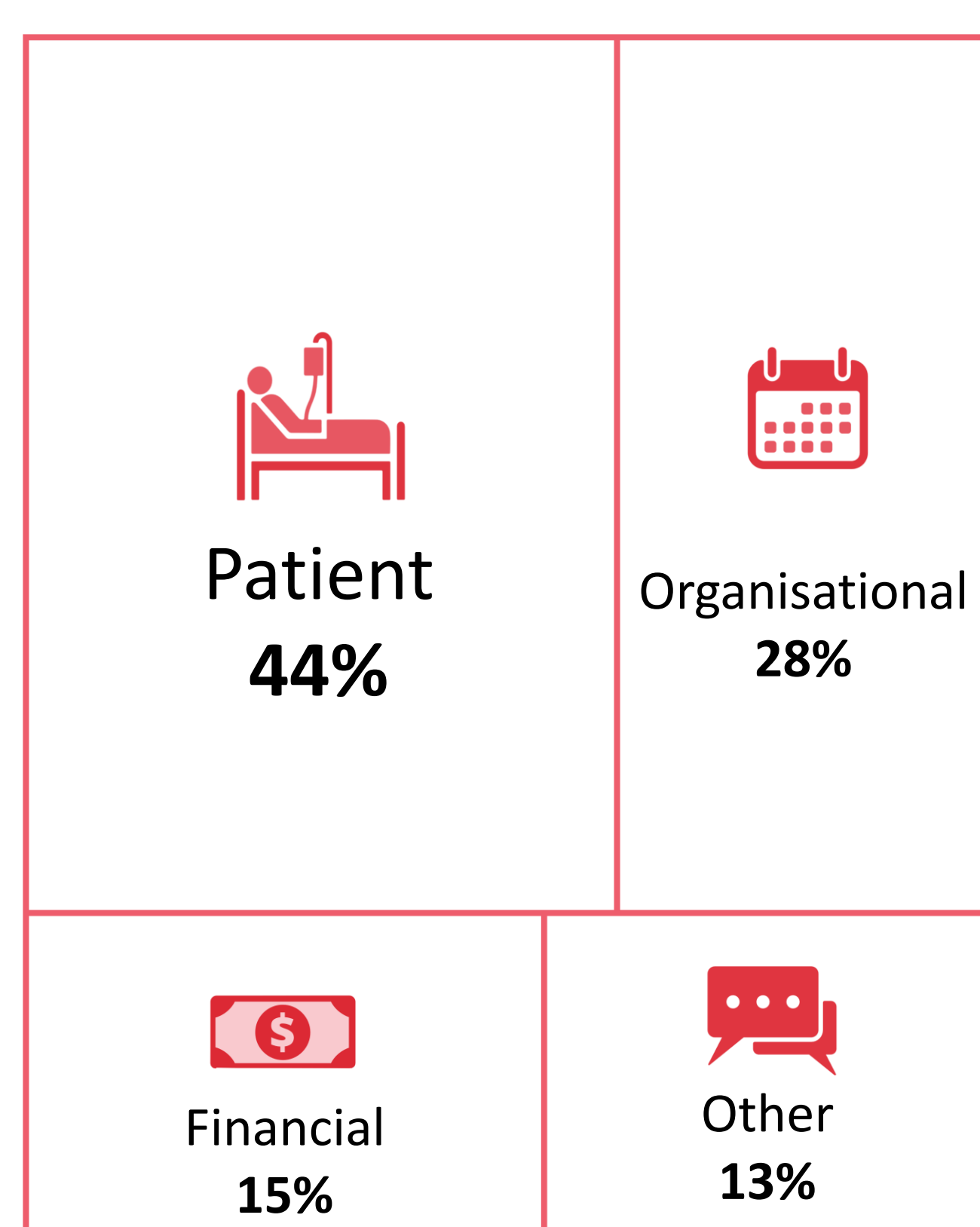
CAPAs formulation for unacceptable risks

### Identification of known or potentials risks

→ 291 potential risks identified with FMEA method for the 7 steps

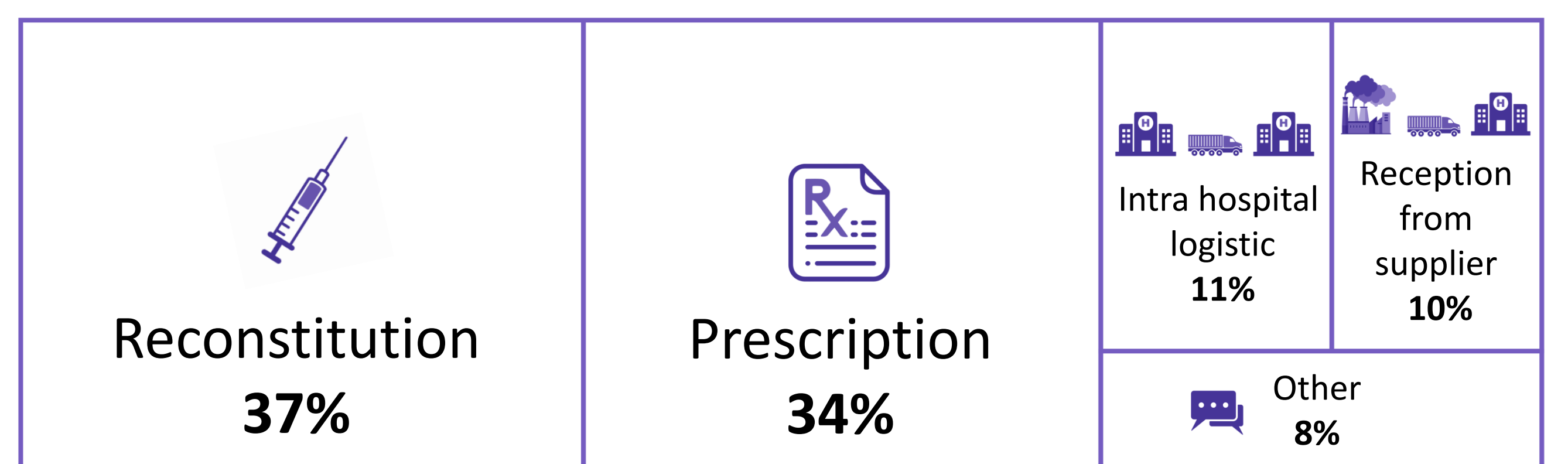
their causes ...

and effects

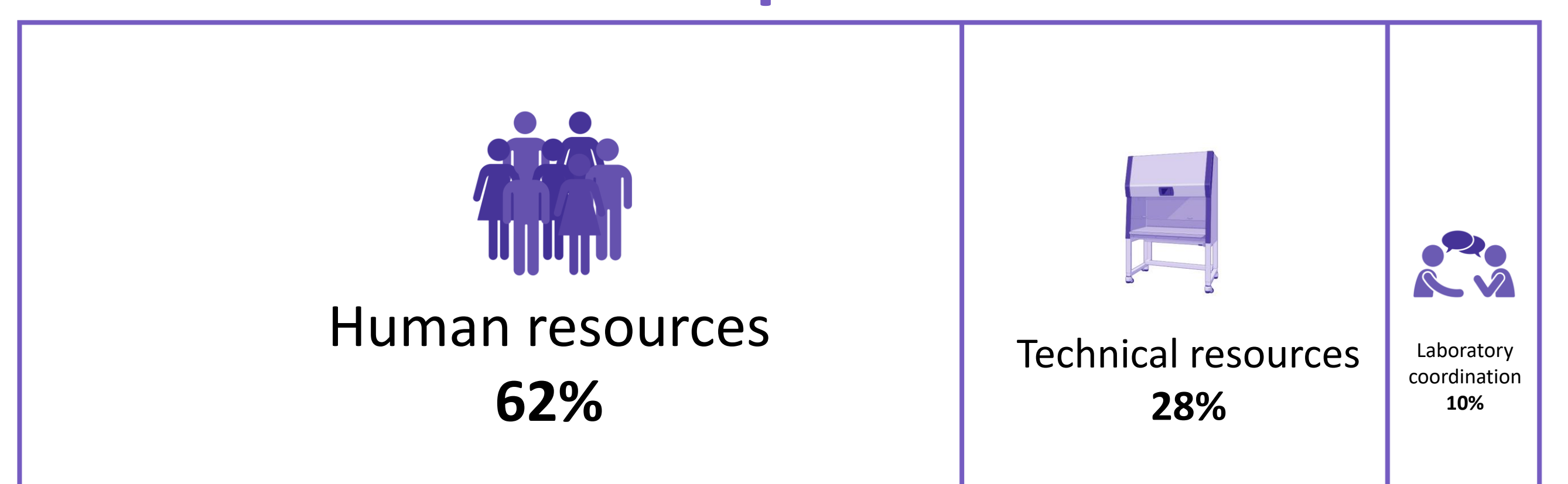


### CAPAs formulation for unacceptable risks

→ 41 CAPAs formulated that concern



and required ...



e.g. : Setting up a dedicated team, creation of a dedicated pharmaceutical compounding unit...

## WHAT IS NEXT ?

- CAPAs monitoring
- Evaluation of the implementation and effectiveness of CAPAs

