# 3º ENCONTRO NACIONAL DE INVESTIGAÇÃO CLÍNICA & INOVAÇÃO BIOMÉDICA

**21 MAIO | ISCTE LISBOA**

AICIB
AGÊNCIA DE INVESTIGAÇÃO CLÍNICA E INOVAÇÃO BIOMÉDICA

fct Fundação para a Ciência e a Tecnologia
Infarmed Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
apifarma Associação Portuguesa da Indústria Farmacêutica
Health Cluster Portugal
PtCRIN Portuguese Clinical Research Infrastructure Network
iscte Instituto Universitário de Lisboa

3° ENCONTRO NACIONAL DE INVESTIGAÇÃO CLÍNICA & INOVAÇÃO BIOMÉDICA

# Digital transformation towards site competitiveness

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# Clinical trials

PHARMACEUTICAL COMPANIES

FDA

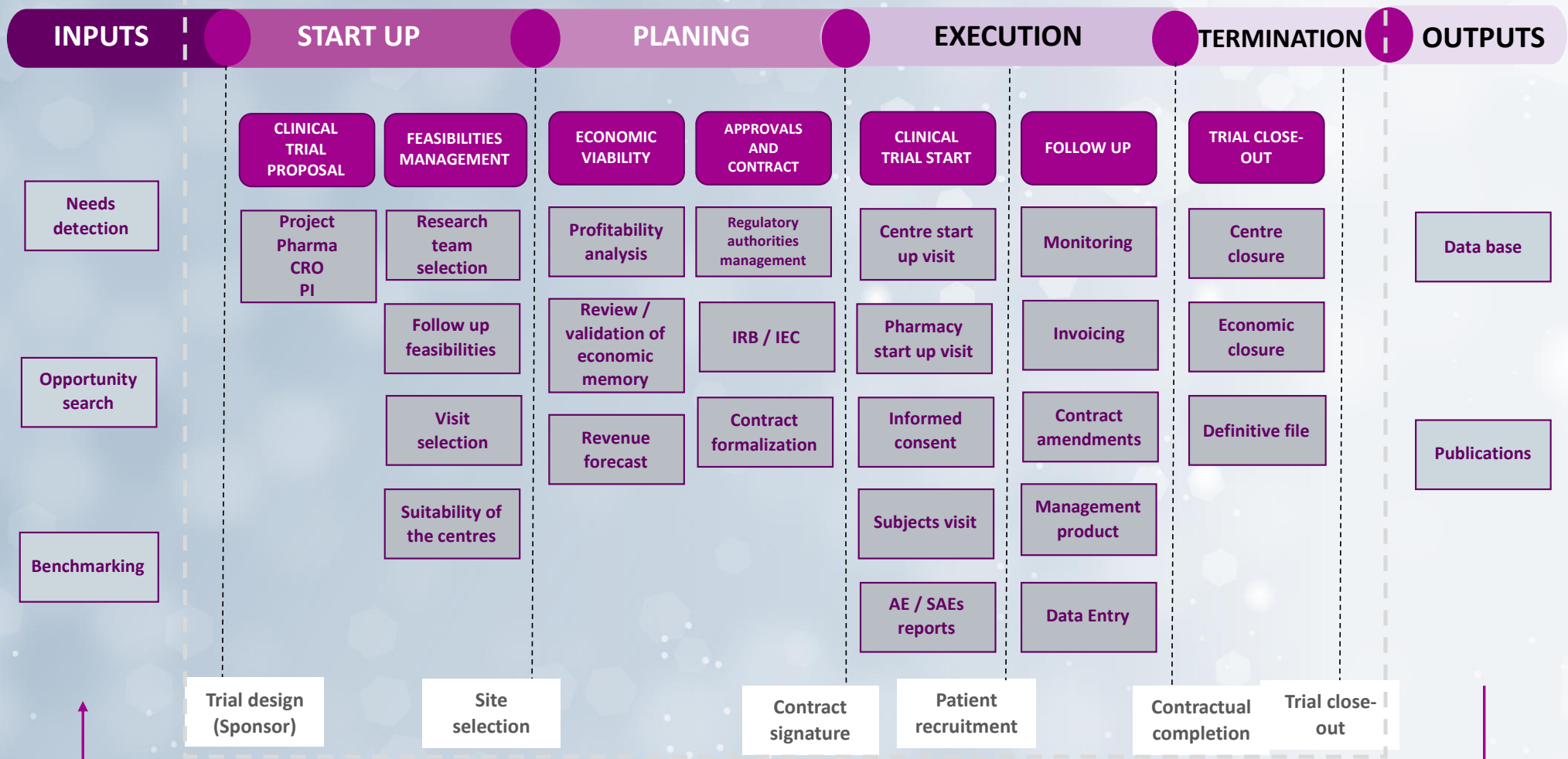
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Internal analysis

We have carried out an internal analysis of our clinical trials workflow and its optimization which include:

- Process
- IT
- Economic
- Stakeholders
- Benchmarking

# Process analysis

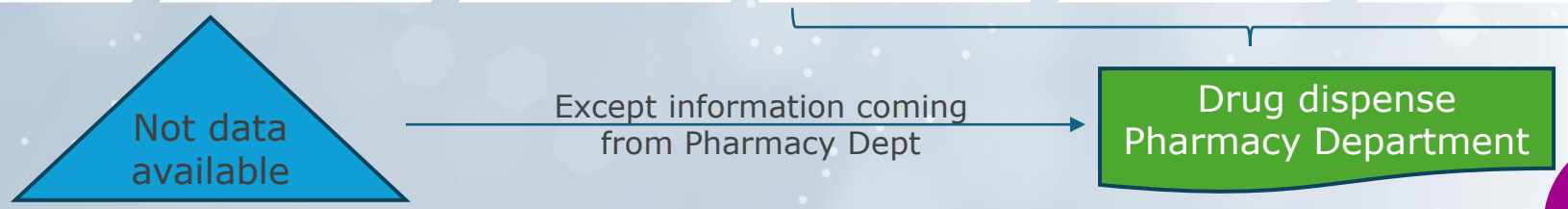


# IT analysis

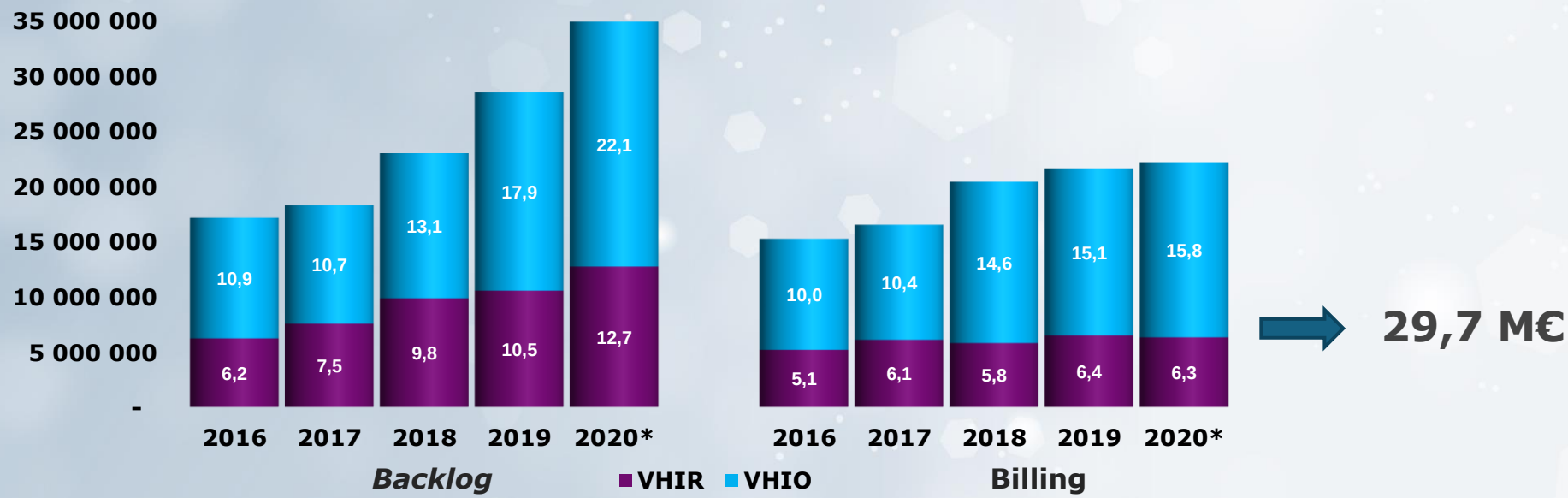

Study registration
Approval: ECs, Legal authorities
Visit to initiate and execute the CTs
Invoicing
Closing and archiving


PIs
Recruitment of clinical trial patients
Study Coordinators, Data Entries, Study Nurses
SAP


Selection visit
Procedures
Screening failure
Protocol visits
Telephone calls
Unscheduled visits
Completion /early term. visit


Not data available
Except information coming from Pharmacy Dept
Drug dispense Pharmacy Department

# Economic analysis




**29,7 M€**

CTs started and closed between 2016 and 2020

| | N | Compromised Pax (N) | Recruited Pax (N) | Backlog (€) | Billing (€) | ≠ |
|---|---|---|---|---|---|---|
| **Total CT** | 280 | 1703 | 1448 | 17.6 M€ | 12.4 M€ | 5.2 M€ |
| **Total recruiting CT** | 202 | 1342 | 1448 | 13.9 M€ | 11.9 M€ | 2 M€ |
| **Total not recruiting CT** | 78 | 361 | 0 | 3.7 M€ | 360 K€ | 3.3 M€ |

# Stakeholders analysis

| Strategic axes → | | Process | | | | | Digitization | | | Spaces | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Actions → | | Centralization of support | Creation of functional support teams | | | Quality plan | Implementation of CTMS/Data | | | Space optimization and reinforcement | | |
| Needs ↓ | | Study coordinators Manager | Start up | Financial follow-up | Closing | Transversal coordination team | Traceability | Invoicing | Dashboard | Increase out patient visit areas | Increase the day care hospital space | Nursing area |
| VHIR | Increase Recruitment | | | | | | | | | | | |
| | Increase Invoincing | | | | | | | | | | | |
| | Decrease Gap Back log vs invoicing | | | | | | | | | | | |
| | Increase Back log | | | | | | | | | | | |
| | Aspects of improvement detected during interviews with PIs (needs): | | | | | | | | | | | |
| HUVH | - Digitization: To have a tracking and traceability tool. | | | | | | | | | | | |
| | - Standardize internal and operational procedures for Study Coordinators | | | | | | | | | | | |
| | - Standardize the process of patient follow-up and management for PIs. | | | | | | | | | | | |
| | - Internal communication: More personalized access with IPs | | | | | | | | | | | |
| | - Detect and manage delays in the negotiation and signing of contracts for clinical trials: Each time slower (15) someone IP has been left out (5) | | | | | | | | | | | |
| | - Invoicing: modify the invoicing follow-up through Econet. | | | | | | | | | | | |
| | - Increase the medical consultation areas on the 13th floor. | | | | | | | | | | | |
| | - Increase the ay care hospital Visit Space on the 13th floor. | | | | | | | | | | | |
| | - Elaborate SOPs to align research with the strategy of CSUR, ERN centers and bring community and non-community patients to be treated at the AACC | | | | | | | | | | | |
| | - Define operations for making test requests to third parties (IDI, laboratories, etc.) and standardize it with the PI's clinical research practice. | | | | | | | | | | | |
| | - Provide nursery service for adult and pediatric patients from clinical trials in the emergency room or hospitalized. | | | | | | | | | | | |
| | - Move towards a model that allows compatibility between IP-dependent SC/DE and other more structural ones. | | | | | | | | | | | |
| | - Pediatrics: Separate it from adults (functional examinations do not have the necessary space on floor 13). | | | | | | | | | | | |
| | - Apply a differential protocol for immunocompromised pediatric patients. | | | | | | | | | | | |
| | - Pediatric hospitalization: search for a framework agreement with the Healthcare Management in order to be able to admit patients included in the clinical procedures required by their protocols. | | | | | | | | | | | |

High impact or direct action

Medium impact or indirect action

# New model

# New model

## Centralized support

- √ **Optimizing human resources**
- √ **Standardizing operational procedures**
- √ **Stabilizing workforces**
- √ **Levering for continuous improvement**

## Digitalization (CTMS)

- √ **Acting as a backbone of all activities and the CT process**
- √ **Providing structure, traceability and accuracy**
- √ **Identifying needs**
- √ **Tracking KPIs, KQIs**

under a Quality Management umbrella…

# Digitalization

## Clinical Trial Management System (CTMS)

To have a trustful tool to register and trace all activity related to clinical trials (CTs). Therefore, we can be sure where every single CT is and what is needed in every moment of its execution.

Outcomes:

a) Improve the knowledge and traceability of the activity.

b) Automate the invoicing of the activity.

c) Obtain indicators through a Power BI dashboard (next upgrade)


Vall d'Hebron

CTMS

fundanet

XOLOMON

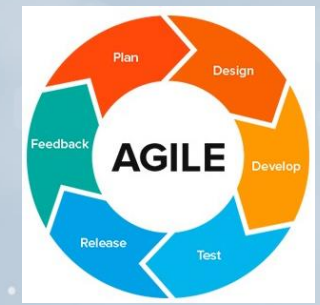
Vault CTMS

# Clinical Trial Management System (CTMS)

## Scope

Develop and implement an strong software that allows to trace all the activity related to the clinical trials process, as well as to obtain indicators through a dashboard.

- Budget module
- Patient visits module
- Billing module
- Dashboard
- Archive

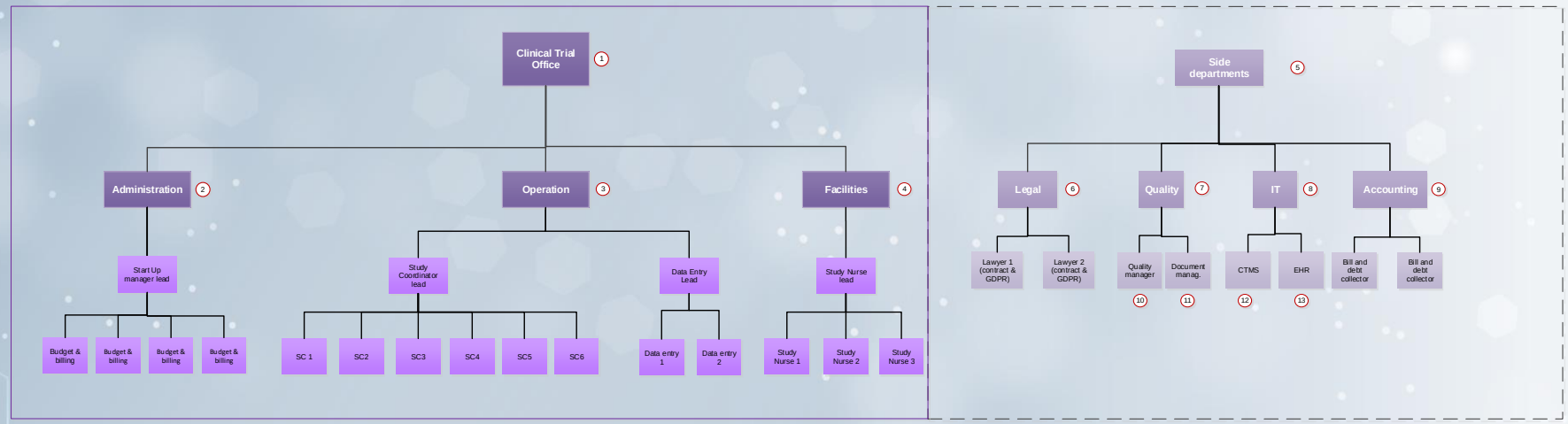


# New model

## Centralized support

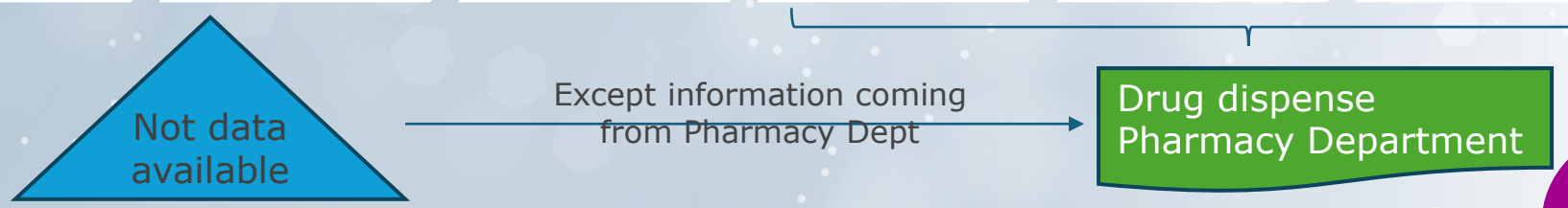
### Advantages

- ✓ Collect needs identification, and manage recruitment and training.
- ✓ Plan onboarding to specialized teams according to needs
- ✓ Offer solutions adapted to common situations: sick leaves, resignations, promotions
- ✓ Strengthening the relationship between the research team and the VHIR support structure.
- ✓ Management and monitoring of information on trial activities

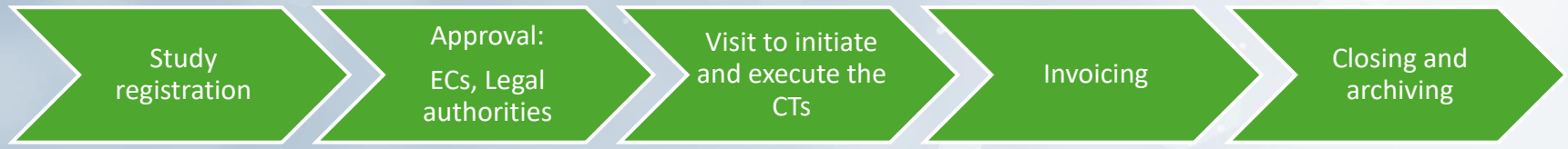


# CTMS outcomes

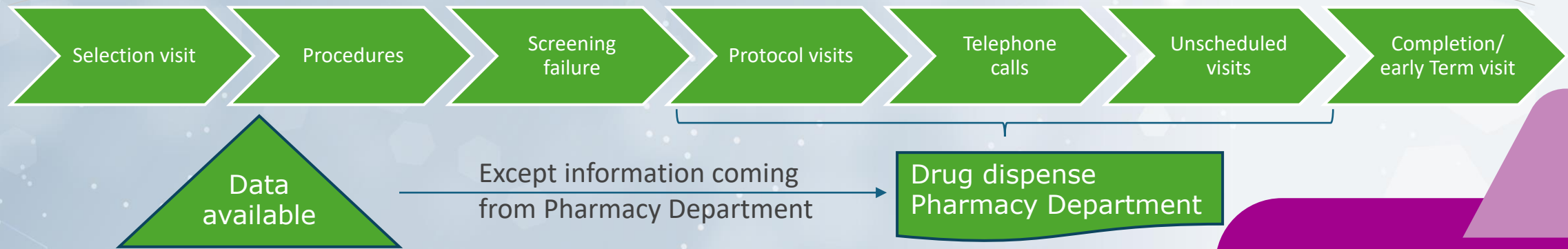


# Benefits of the CTMS







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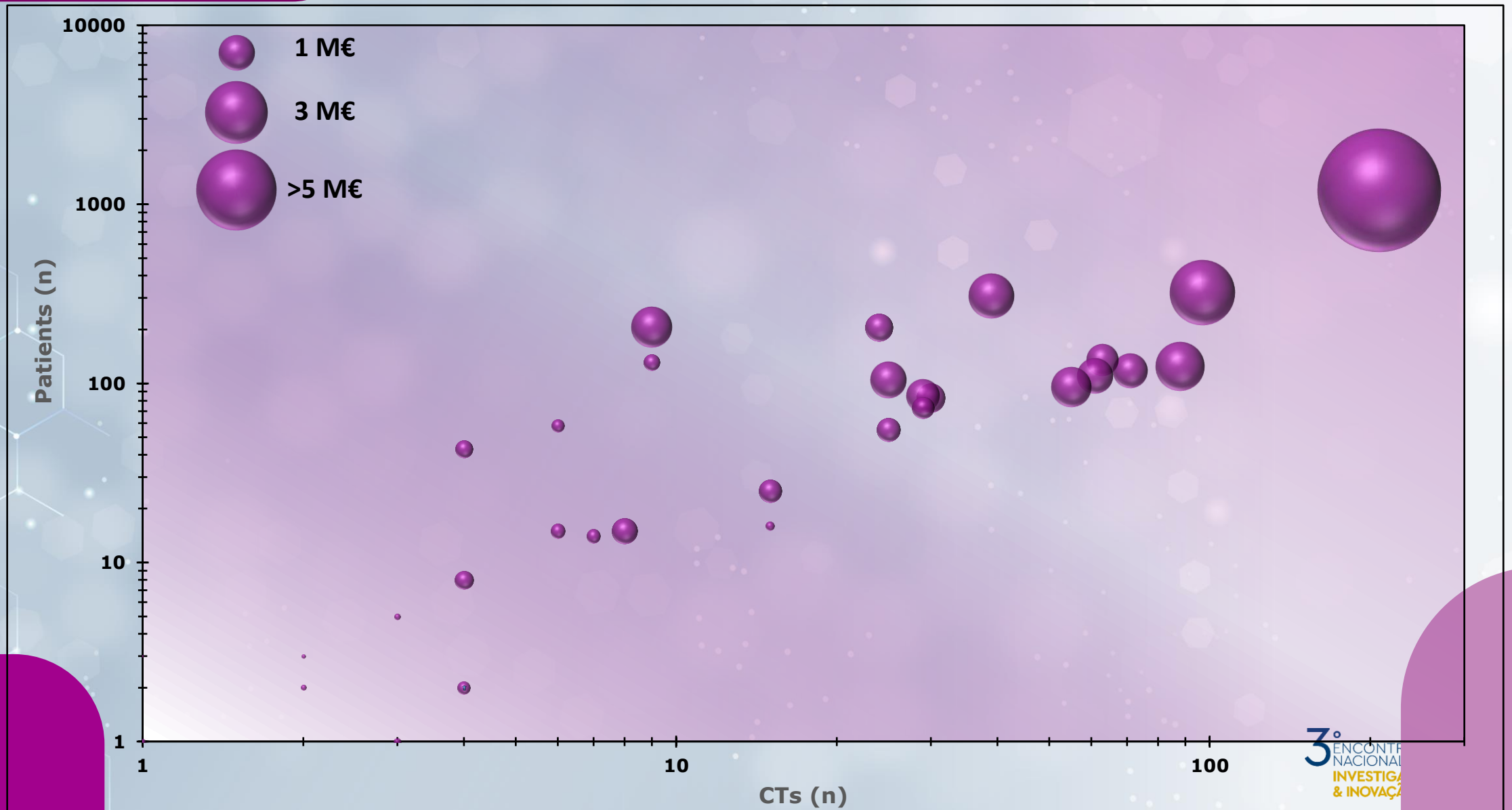

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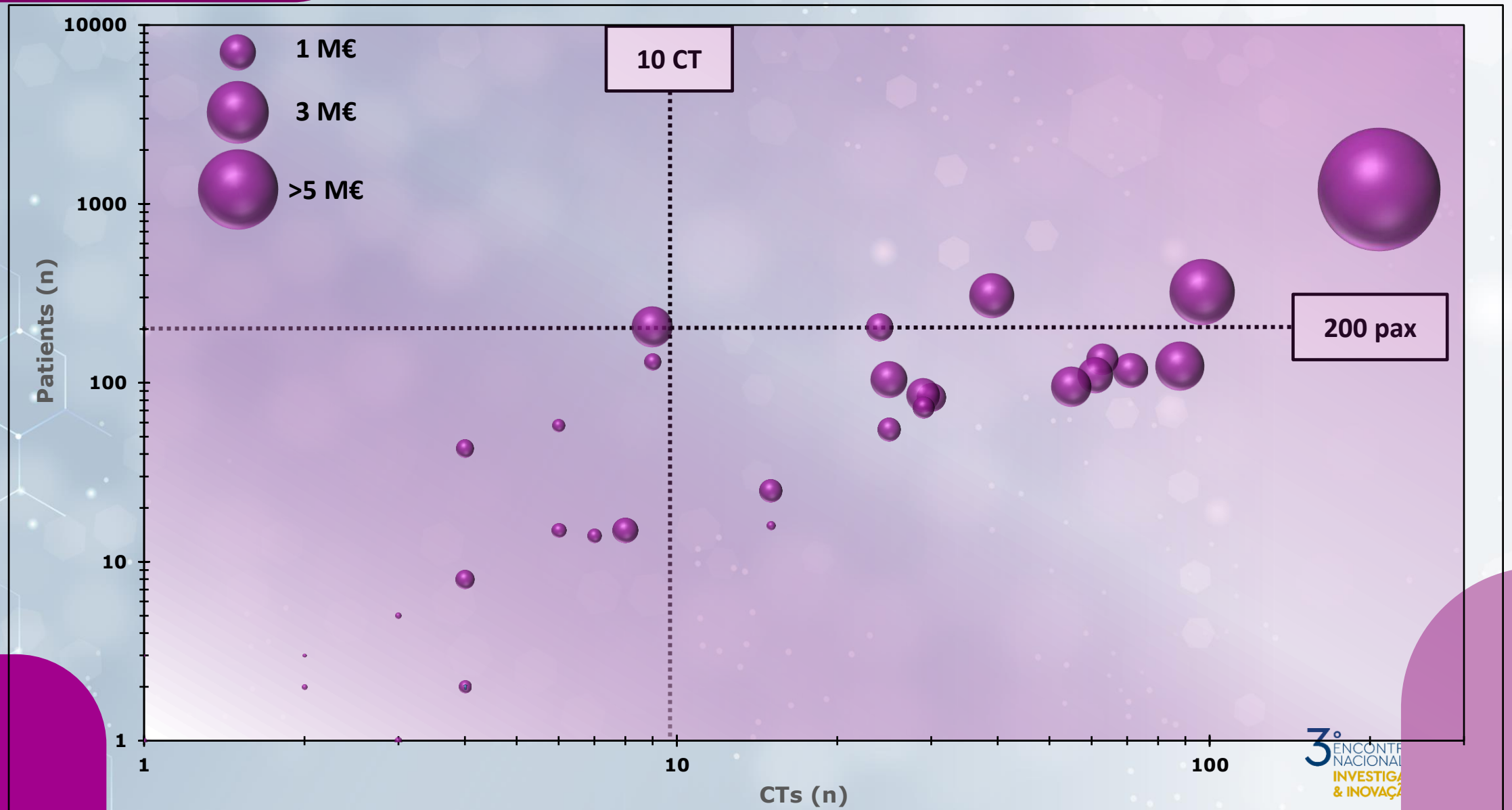
10000
1000
100
10
1
Patients (n)
1 M€
3 M€
>5 M€
10 CT
200 pax
1
10
100
CTs (n)

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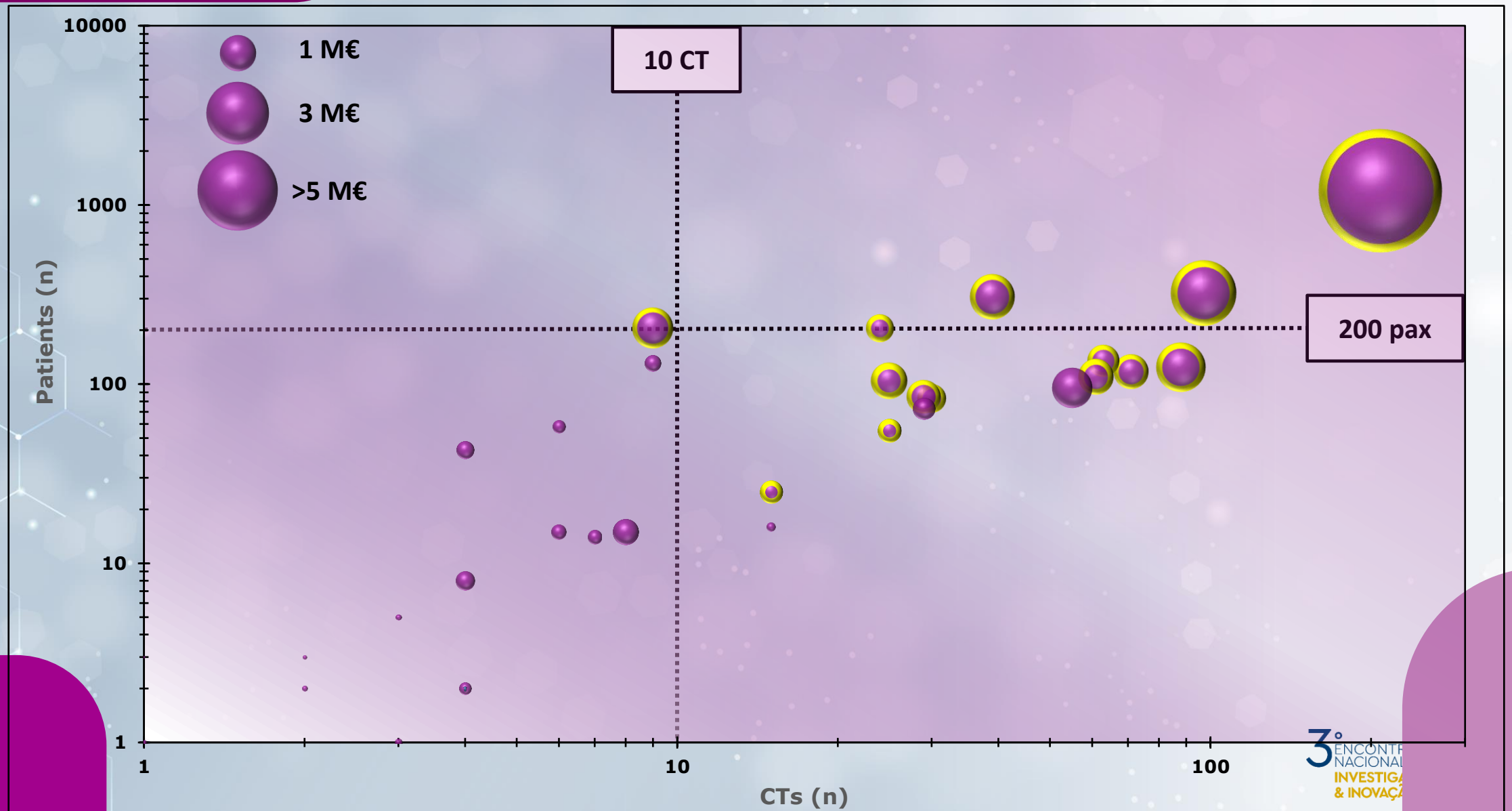
10000
1000
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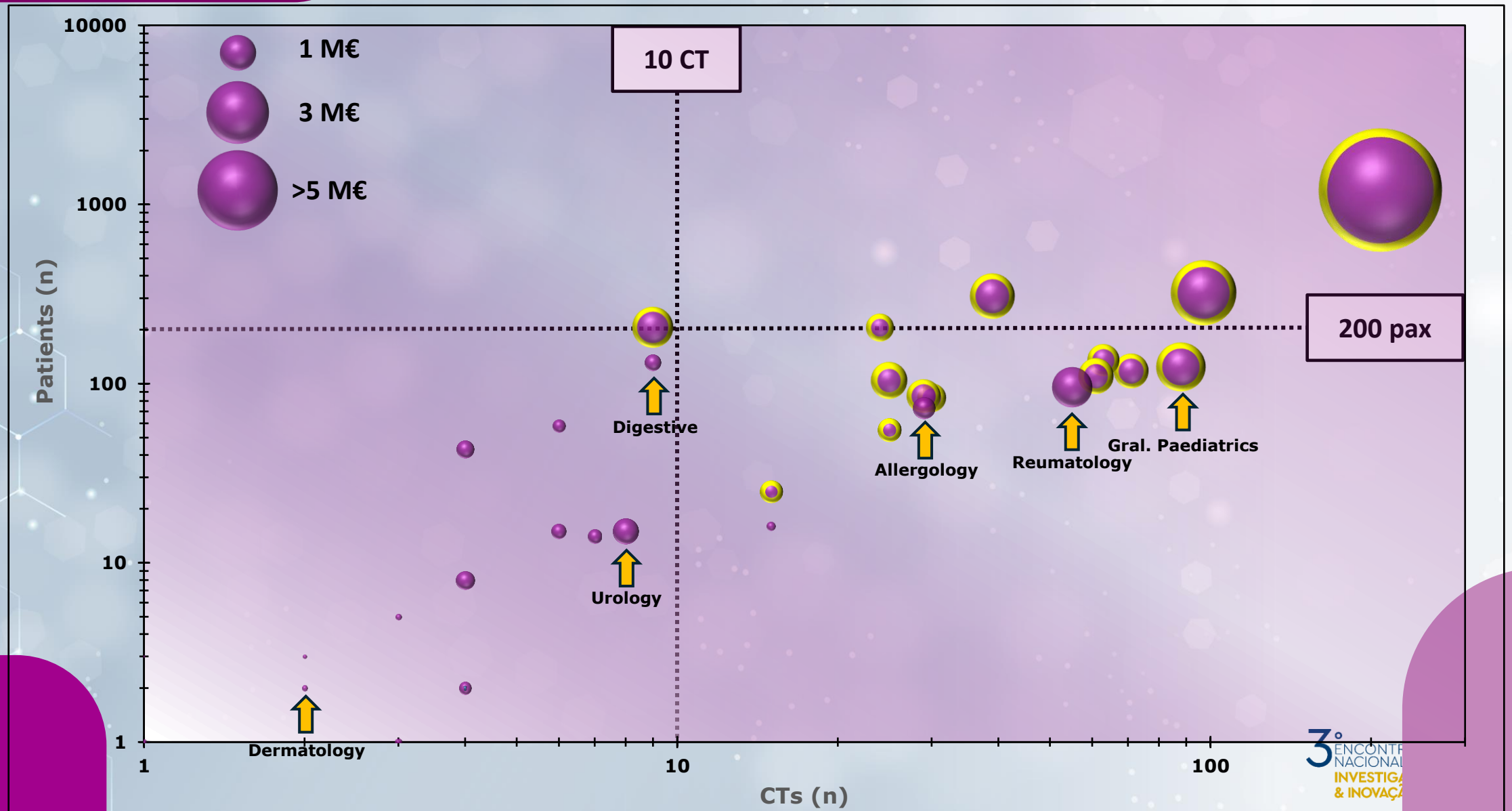
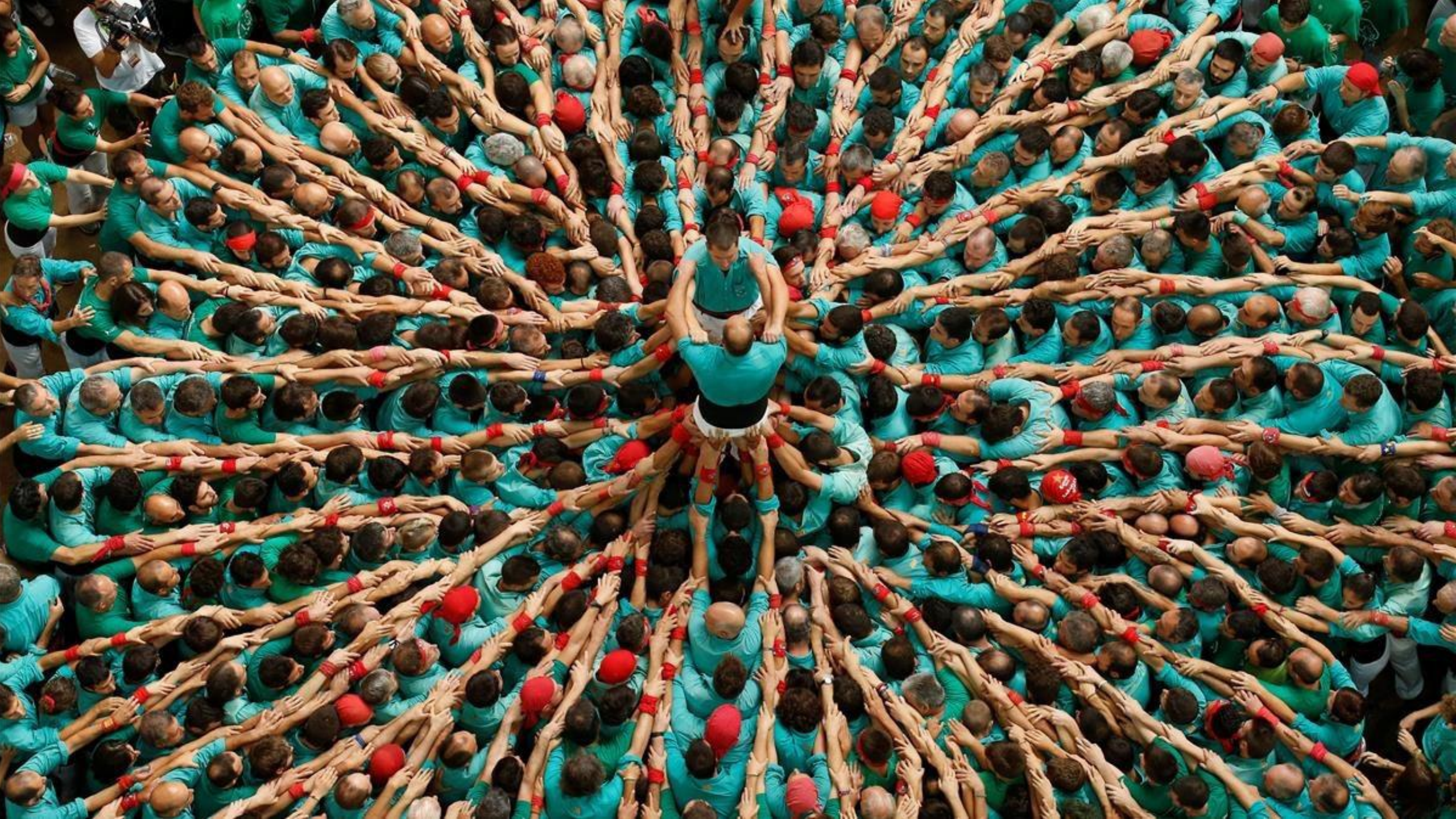
1
Patients (n)
1 M€
3 M€
>5 M€
10 CT
200 pax
1
10
100
CTs (n)

# By Dept.


10000
1000
100
10
1
Patients (n)
1 M€
3 M€
>5 M€
10 CT
200 pax
Digestive
Urology
Dermatology
Allergology
Reumatology
Gral. Paediatrics
1
10
100
CTs (n)



# Thank you for your time.