



# ERICA

European Rare Disease Research  
Coordination and Support Action

## ERICA GA 2023 WP2 Session Current status of ERN Registries & WP2 activities

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Thursday 6<sup>th</sup> July 2023

# Introduction

 WP2

## Data Collection, Integration and Sharing

WG Data collection

WG Legal aspects

WG Interoperability

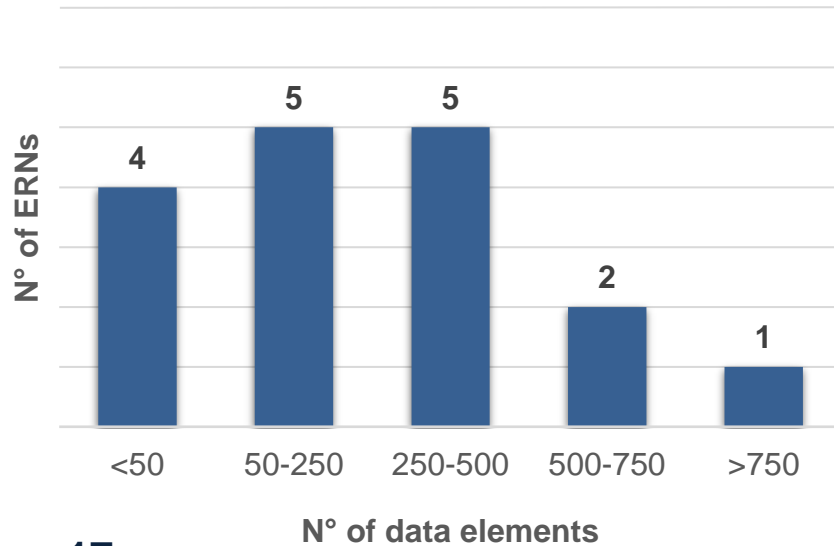
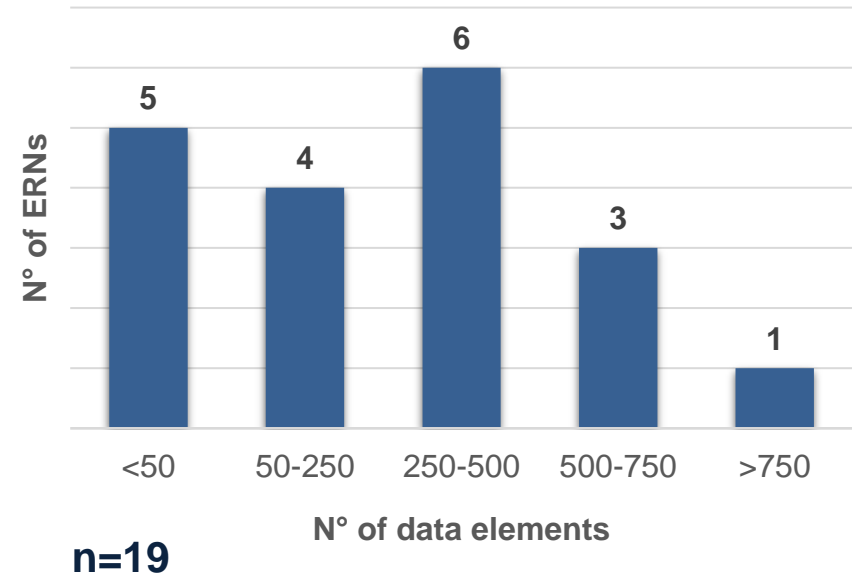
WG Secondary data use

- Establish common guidelines for **collecting, reusing** and **sharing** data across ERNs and with other different stakeholders
- Encourage interoperability and standardisation

### Data capture as starting point:

- Definition of data elements tied to registry objectives
- Data elements need to be clearly defined to ensure consistency in interpretation across participating sites
- Need to balance collected elements with the burden associated with data collection

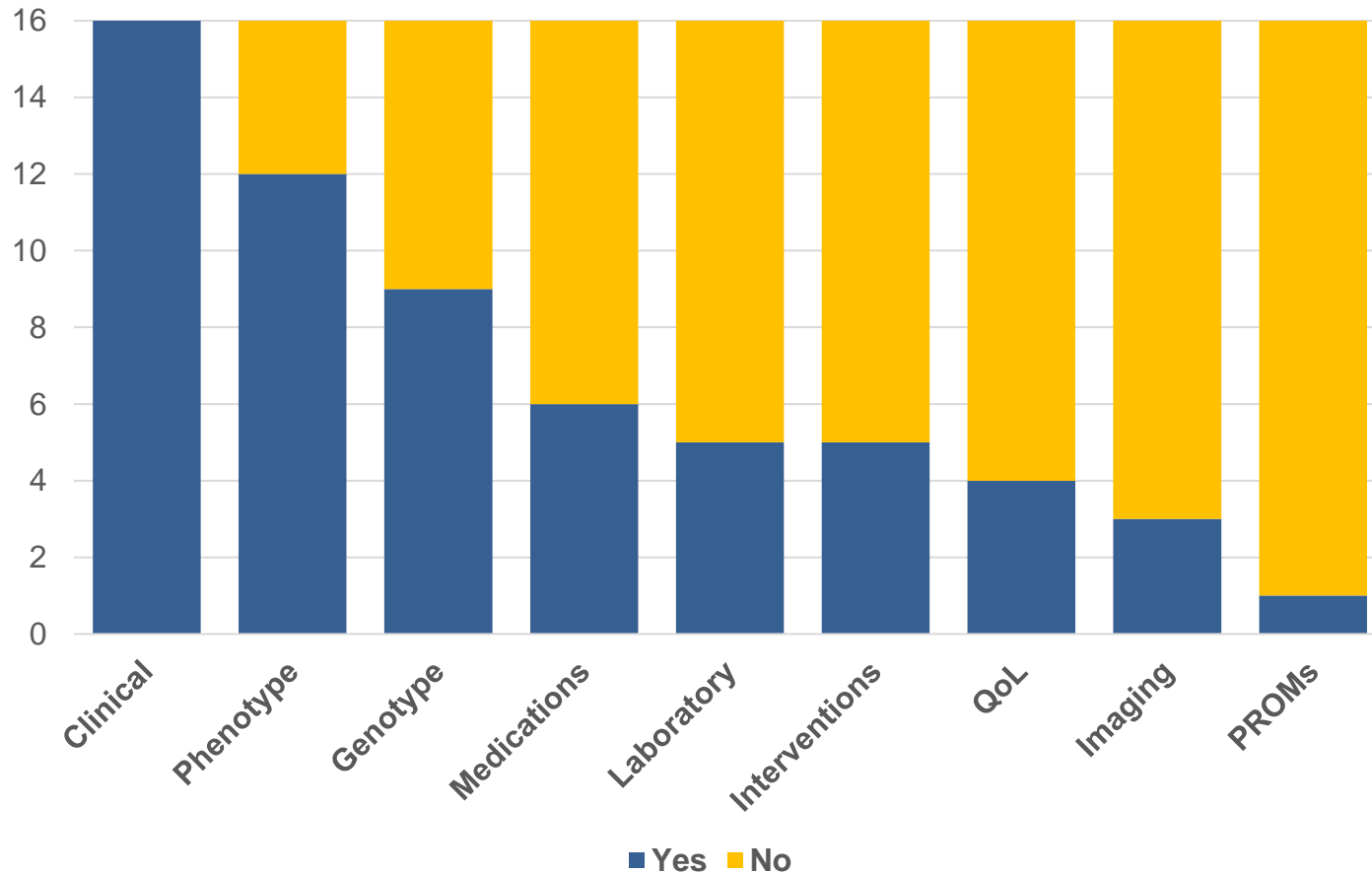
# ERN Data Dictionaries for Data Capture

**2021**

**2023**


- Large variance in number of data elements (18 to >1.000)
- ERNs continue to tailor and expand the scope of captured data elements

# ERN Data Dictionaries for Data Capture

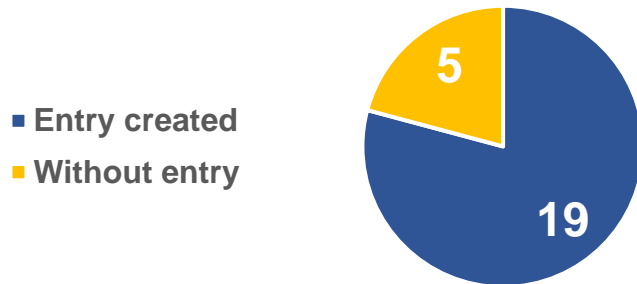
Type of data elements collected



n=16

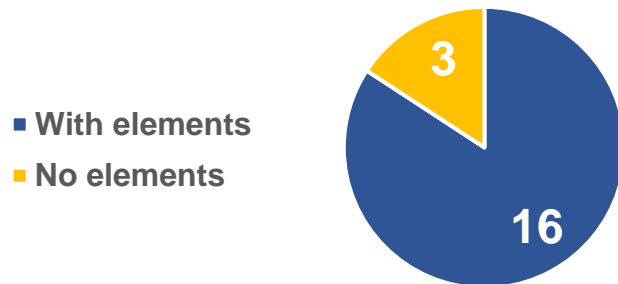
# ERN Data Dictionaries for Data Capture

ERNs with entries in ERDRI.mdr

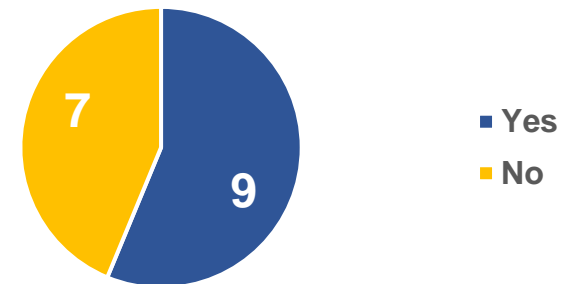


<https://eu-rd-platform.jrc.ec.europa.eu/mdr/>

ERN data dictionaries in ERDRI.mdr



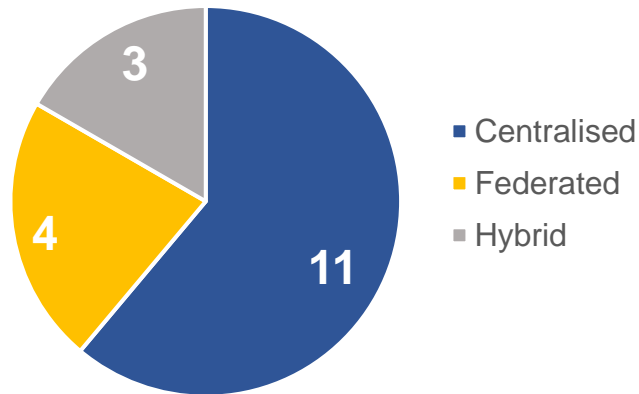
Updated within the last 6 months



➤ **Milestone 8:** upload of ERN data dictionaries to ERDRI.mdr

# ERN Registries

Types of ERN Core Registries

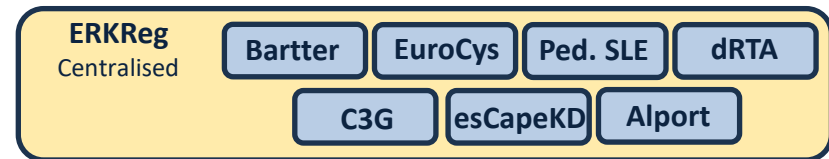


Some ERNs manage disease-specific registries in addition to their core registries:

- Separate from the core registry, with different approaches (e.g., VASCERN)



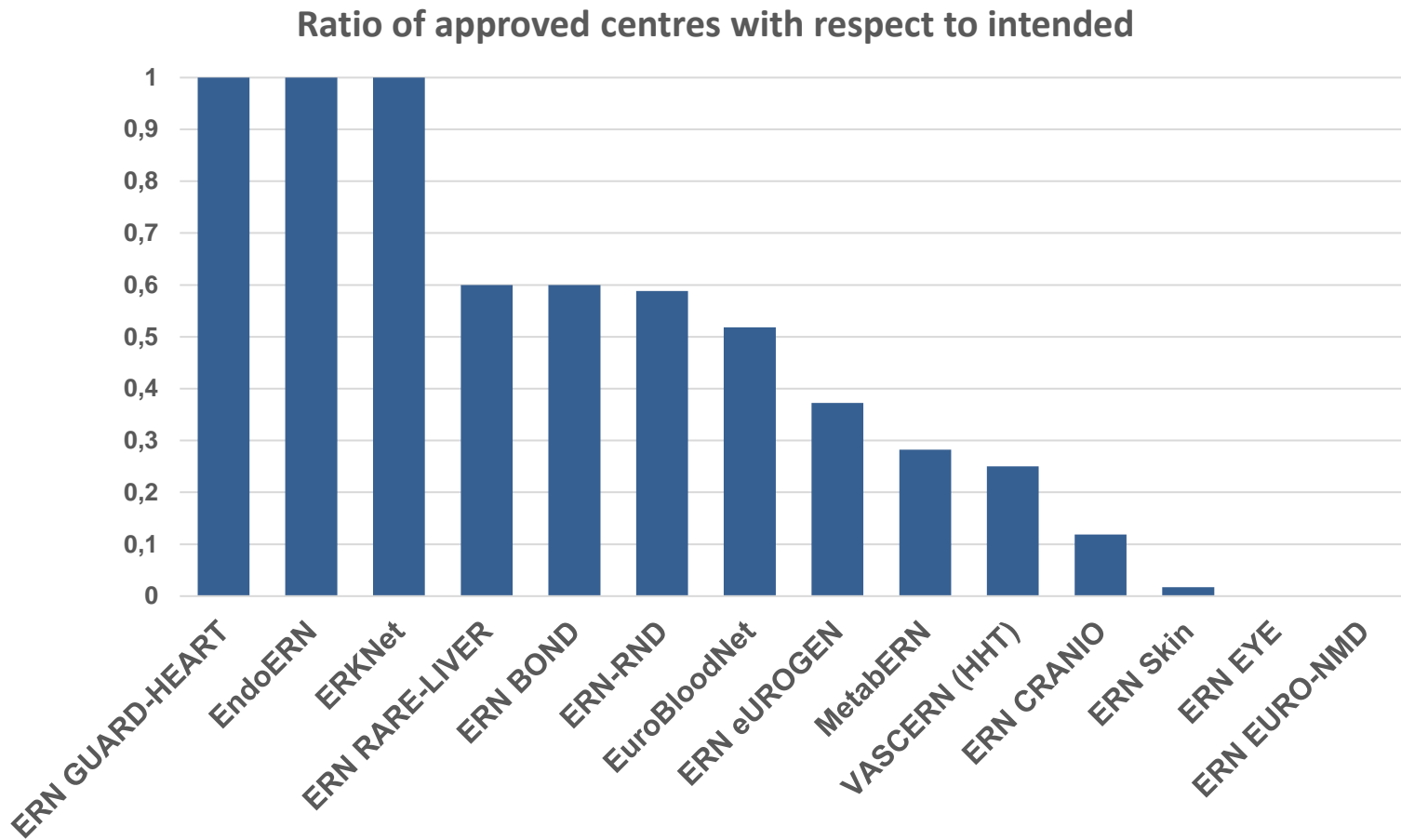
- Modularly integrated within the same infrastructure as subregistries (e.g., ERKNet)



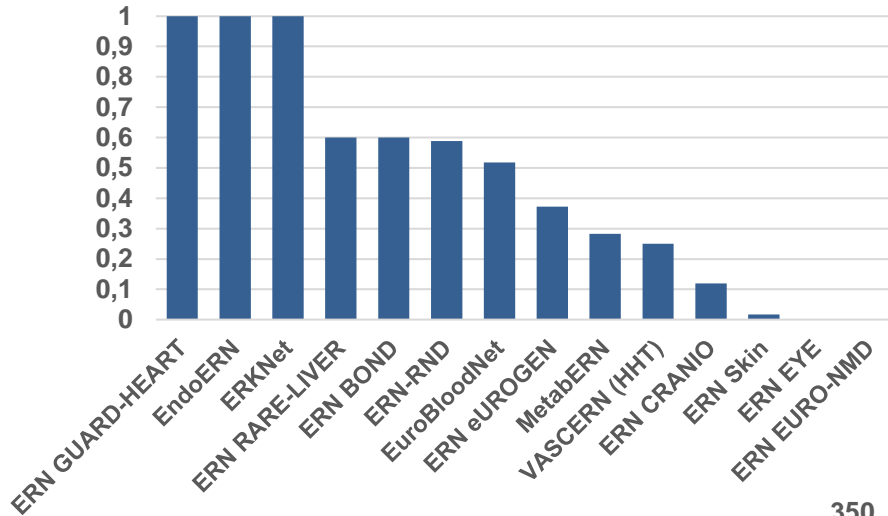
## Choice of implementation

|                | Molgenis | Castor | RedCap | Other provider | Own system |
|----------------|----------|--------|--------|----------------|------------|
| Number of ERNs | 4        | 3      | 4      | 7              | 5          |

## Centre participation in ERN registries

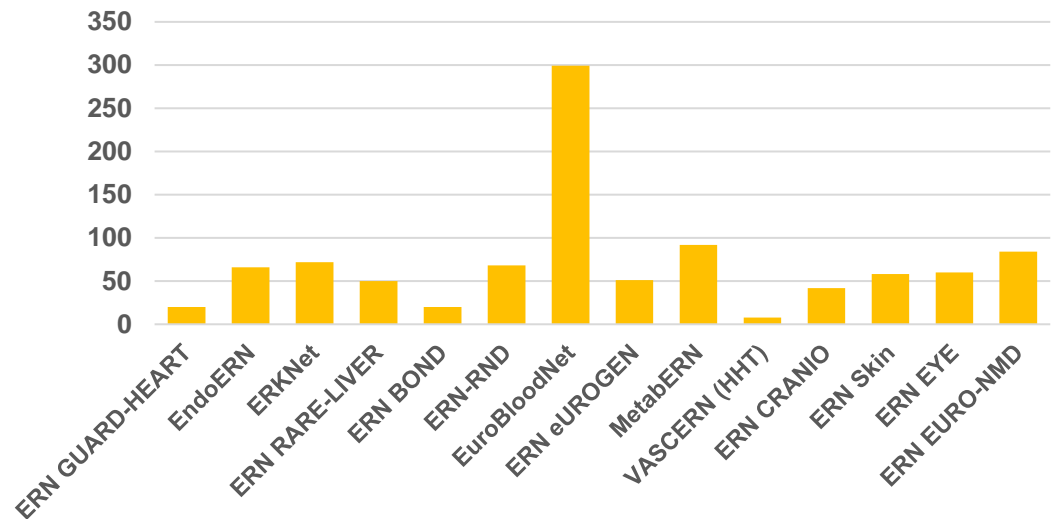


Ratio of approved centres with respect to intended



➤ Consider overall participation projections!

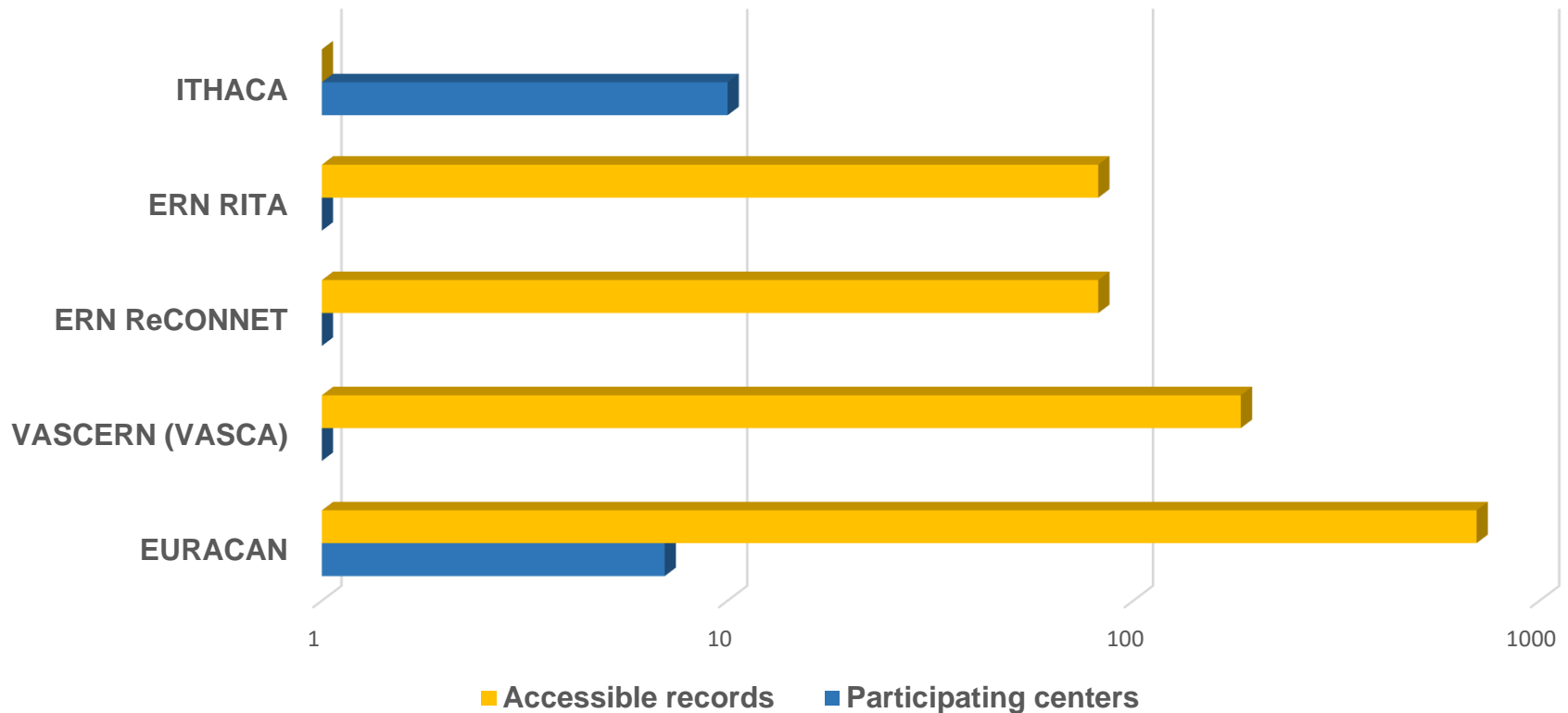
Centres intended to participate



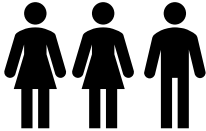

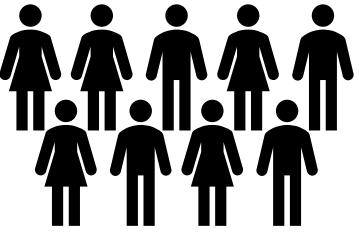


## Centre participation in ERN registries

Accessible records and centre participation in federated ERN registries



## Progression of Patient Enrolment

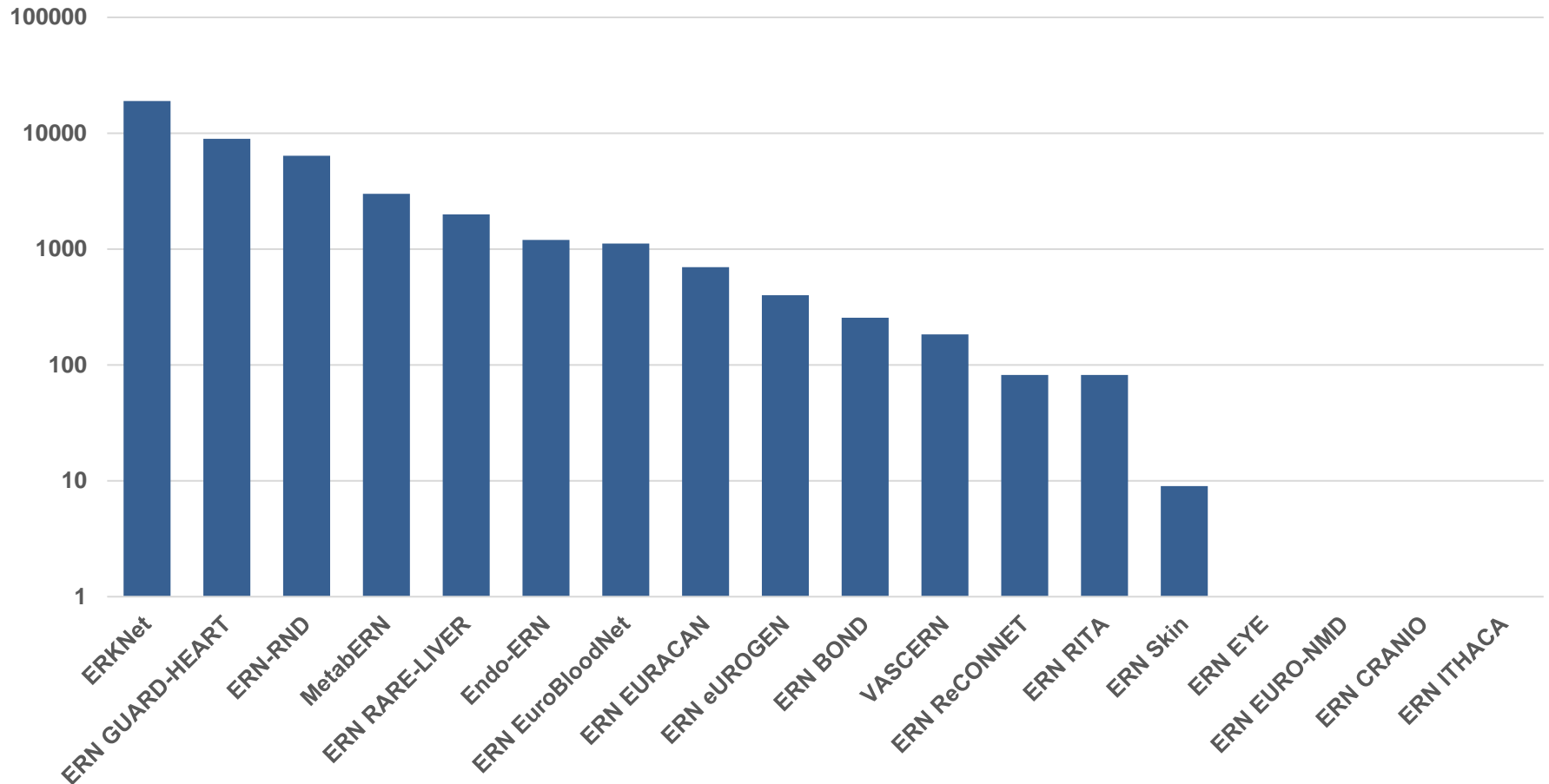
|  | Number of patients enrolled | Number of ERN Registries |      |      |      |
|--|-----------------------------|--------------------------|------|------|------|
|  |                             | 2020                     | 2021 | 2022 | 2023 |
|   | <100                        | 17                       | 13   | 10   | 8    |
|    | 100-1.000                   | 4                        | 5    | 5    | 3    |
|  | >1.000                      | 3                        | 4    | 9    | 7    |

In Oct.22, at least 4 registries contained >10.000

**1.000-5.000**  
 4 Reg.

**5.000-10.000**  
 2 Reg.

**>10.000**  
 1 Reg.  
**Surveyed!**

**Number of patients currently enrolled in surveyed registries**


# Data reuse and access

- Standardized, GDPR compliant, machine readable Informed Consent Form in all EU languages.
- Standardized Collaboration / Data Transfer / Data Sharing Agreements
- Harmonized Data Access Policy

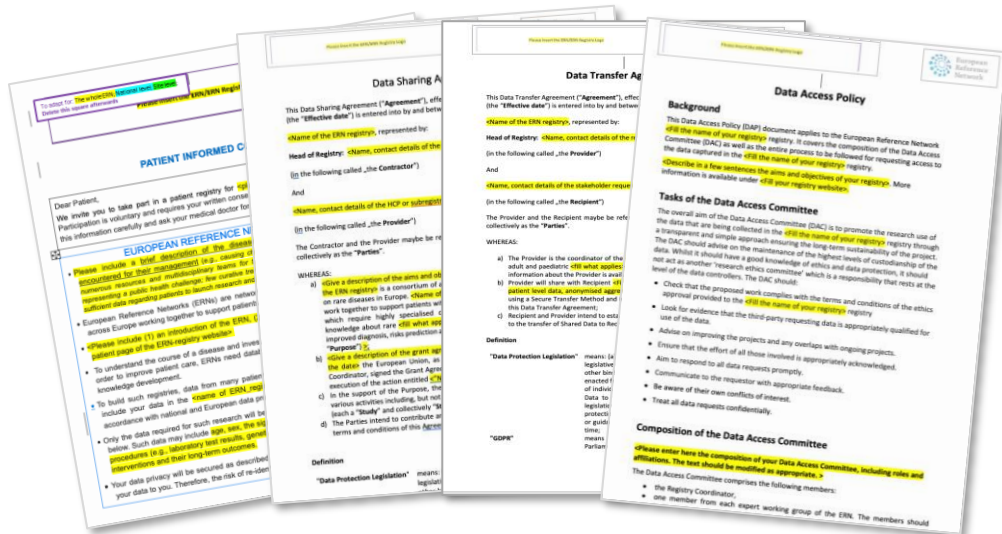
**Issues when sharing aggregated data:**

- Different legal frameworks
- Sufficiently anonymised?
- Does it qualify as personal or non-personal data?



**Establish common guidelines for ERNs:**

- Review applicable regulations
- Methods to prevent re-identification
- Discussion of obfuscation techniques



## FAIRness in ERN registries

- The **FAIRification Stewards team** was established with the goal to help ERNs apply the **FAIR** principles (**F**indability, **A**ccessibility, **I**nteroperability and **R**eusability) to their patient registries.
- **Implementation inventory** with 94 tools, addressing different phases of the FAIR process:
  - Data Modelling
  - Data Collection
  - Registry registration
  - Data Accessing
  - Data Querying).

### Collaboration between FAIRification stewards and ERNs resulted in:

- Increase in implementation of FAIR tools.
- Most of the new implementations appears to have happened in response to guidance and information provided about previously unknown tools.
- Future work to be directed to the areas of querying and accessing data.

## FAIRness in ERN registries: Data Access

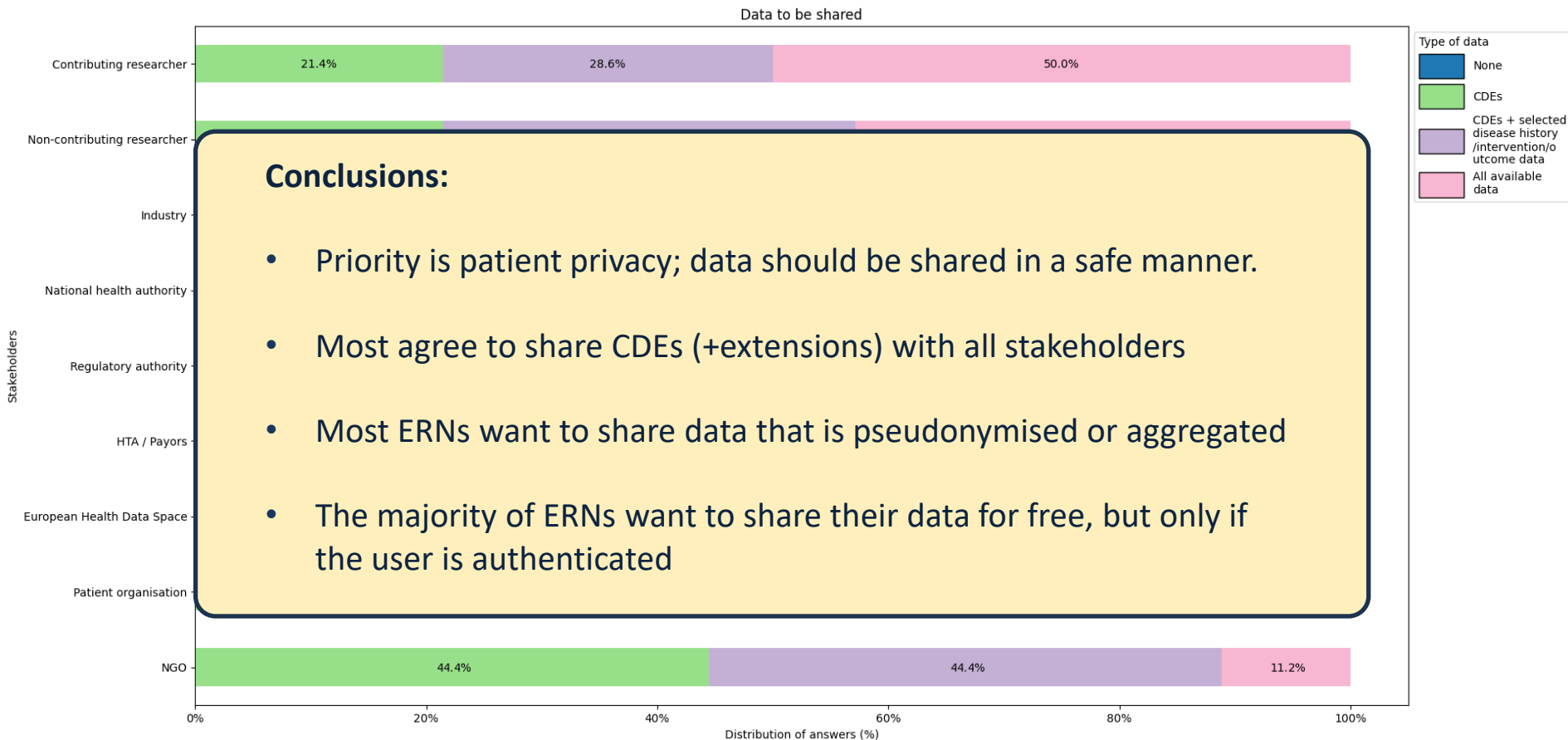
- In 2022, ERNs were requested to describe their preferences respect to:
  - Which data to share
  - How to share it
  - Whom to give access to it
  - Time of publication
  
- Stakeholders considered:
  - Contributing researcher
  - Non-contributing researcher
  - Industry
  - National Health Authority
  - Regulatory authority
  - Health technology Assessment
  - European Health Data Space
  - Patient Organisation
  - Non-Governmental Organization

Definition of **access conditions** is a crucial step in the journey to FAIRness!

# FAIRness in ERN registries



# FAIRness in ERN registries





## **ERICA Deliverable: Monitoring Report on ERN Data Collection**

- Determine development stage of ERN registries
- Review methods for data entry into the registries
- Obtain a clearer view of implemented data quality frameworks
- Consider overall sustainability of the data collection process

### **Open discussion:**

- Identification of challenges or barriers faced during implementation of the registries
- Suggestions for improving collaboration and communication among ERNs

Please go to [menti.com](https://menti.com) and use the code:

**2652 7361**

Or scan:

