

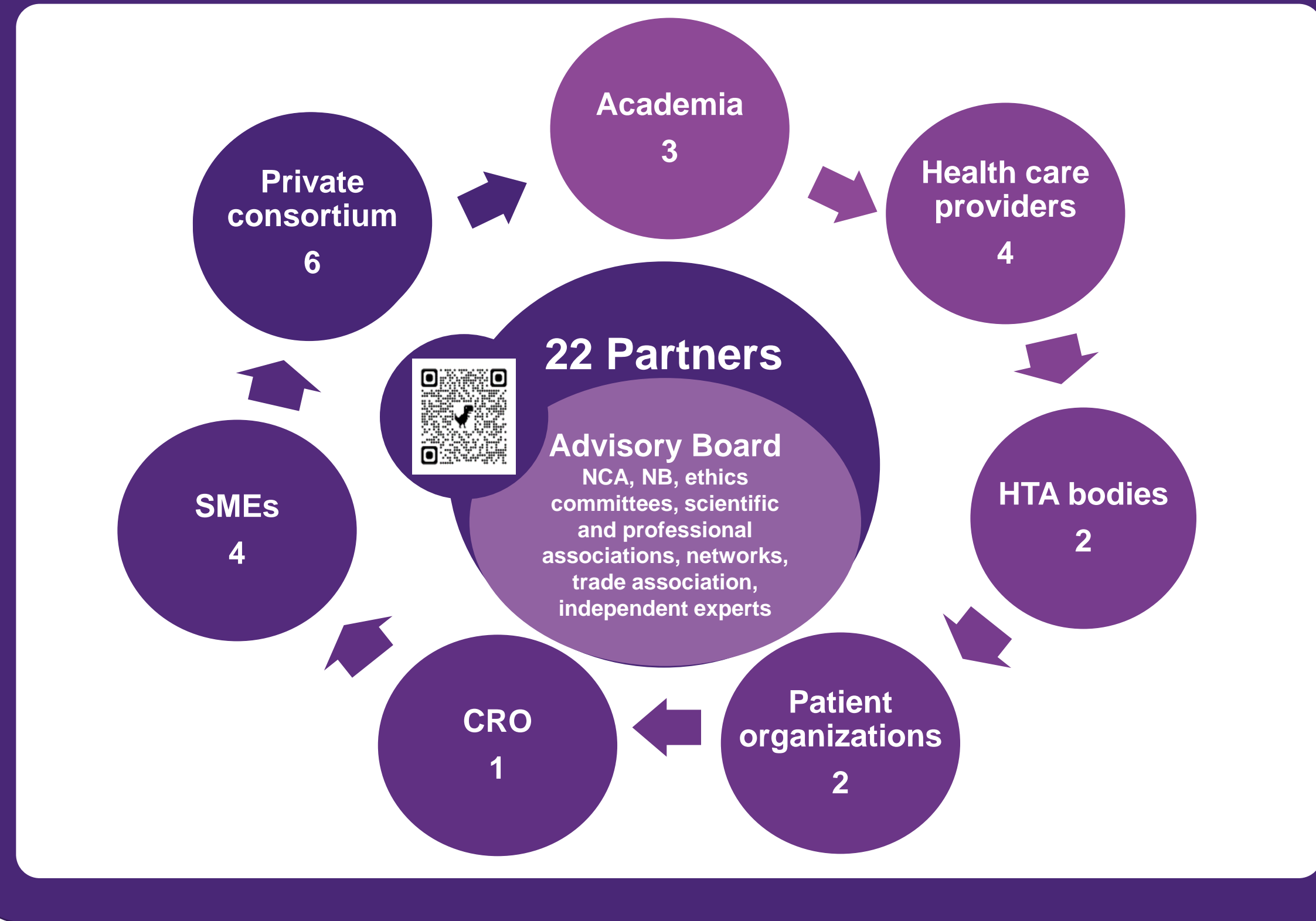
# Use of Early Feasibility Studies to Inform Development of Medical Devices

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## AIMS OF HEU-EFS PROJECT

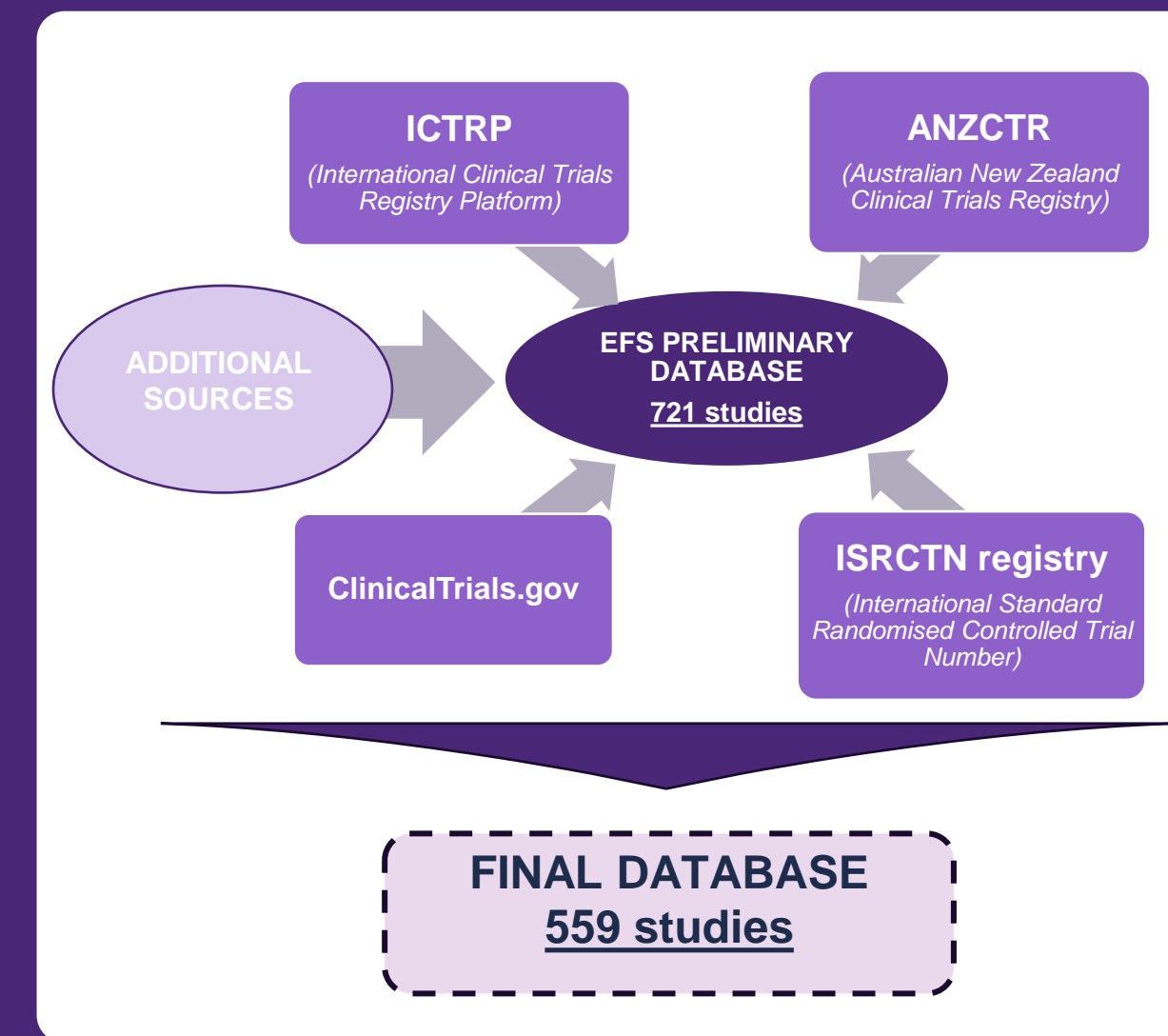
Formulate recommendations for the establishment of an Early Feasibility Studies Program (EFS) within the EU, ensuring patient safety and enhancing the EU single market competitiveness.



## INTRODUCTION & OBJECTIVE

- EFS are limited clinical investigations aimed at evaluating design concepts concerning initial clinical safety and functionality, potentially informing design modifications (ISO 14155:2020).
- In the USA, the FDA launched an EFS Program in 2013.
- Lack of public registries of EFS and limited evidence on their use and impact.
- This study investigated the characteristics of EFS conducted for medical devices globally.

## METHODOLOGY



1. Search of EFS-like studies in public registries (ClinicalTrials.gov, ICTRP, ANZCTR, ISRCTN Registry) and additional sources (CMS.gov, literature review, specialized news sites, Callea et al, 2022).

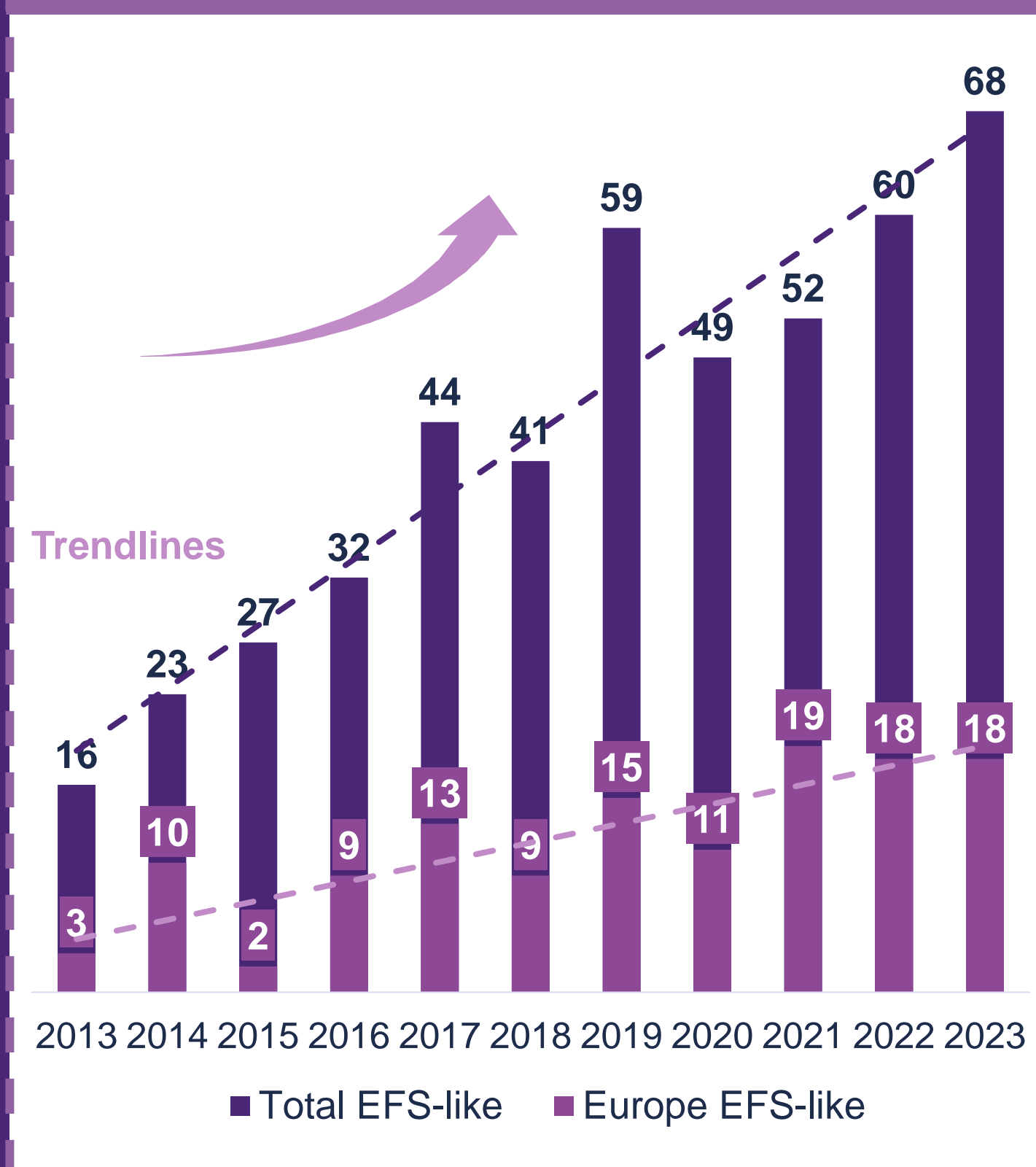
### EFS-LIKE INCLUSION CRITERIA

1. EFS: description in title or summary of the study as «early feasibility» or «EFS» OR
2. EFS-like:
  - Study type: **Interventional**;
  - Estimated sample size  $\leq 30$ ;
  - **Non-randomized** allocation
  - **Interventional mode: single group assignment**;
  - **Masking: None (Open label)**

2. Survey on EFS sponsored by Consortium Partners. 1-to-1 interviews to validate and integrate results.

## RESULTS

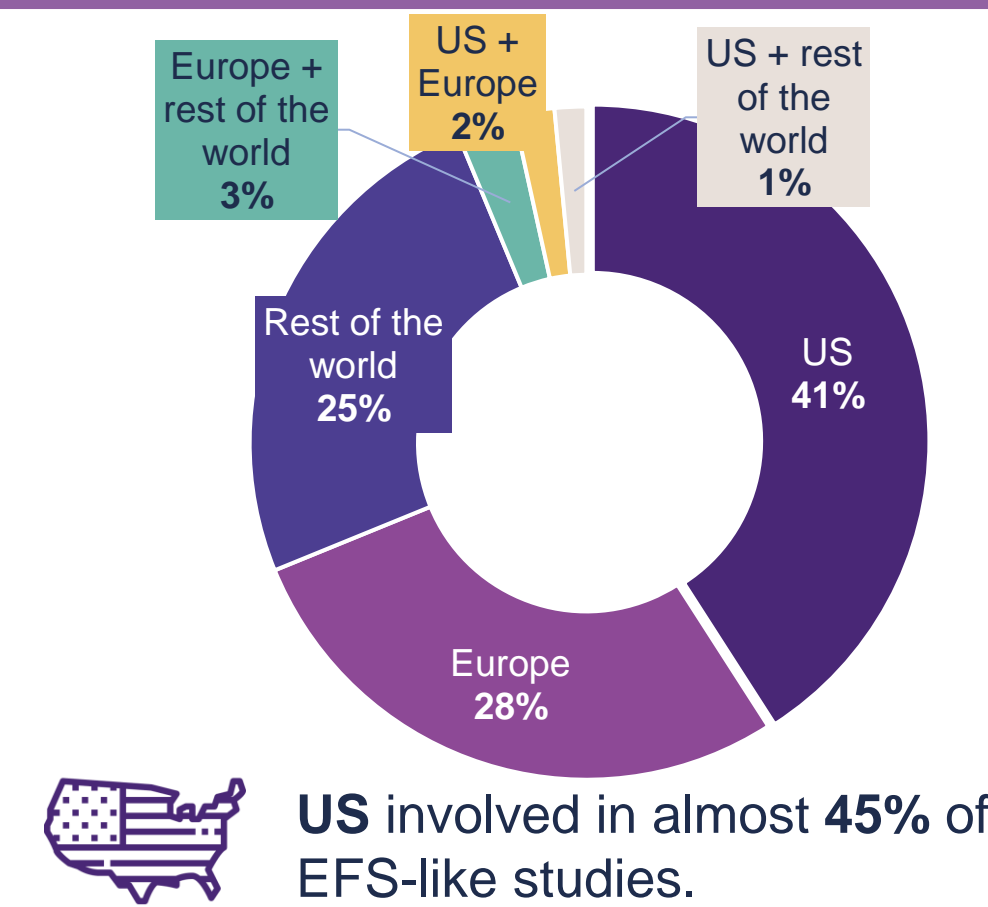
Time trend of EFS-like studies 2013-2023 (start year of the study)



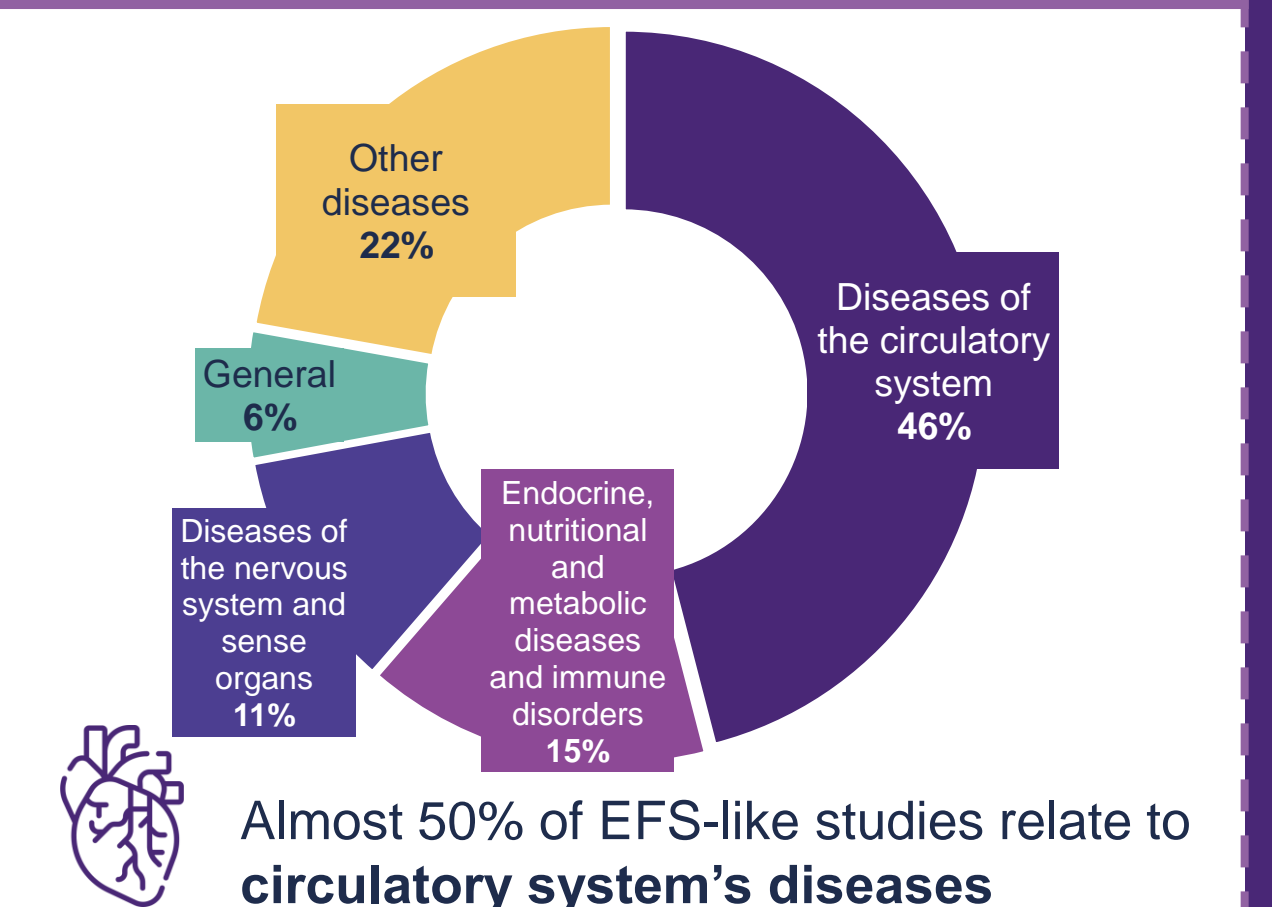
EFS-like studies in Europe 2013-2023



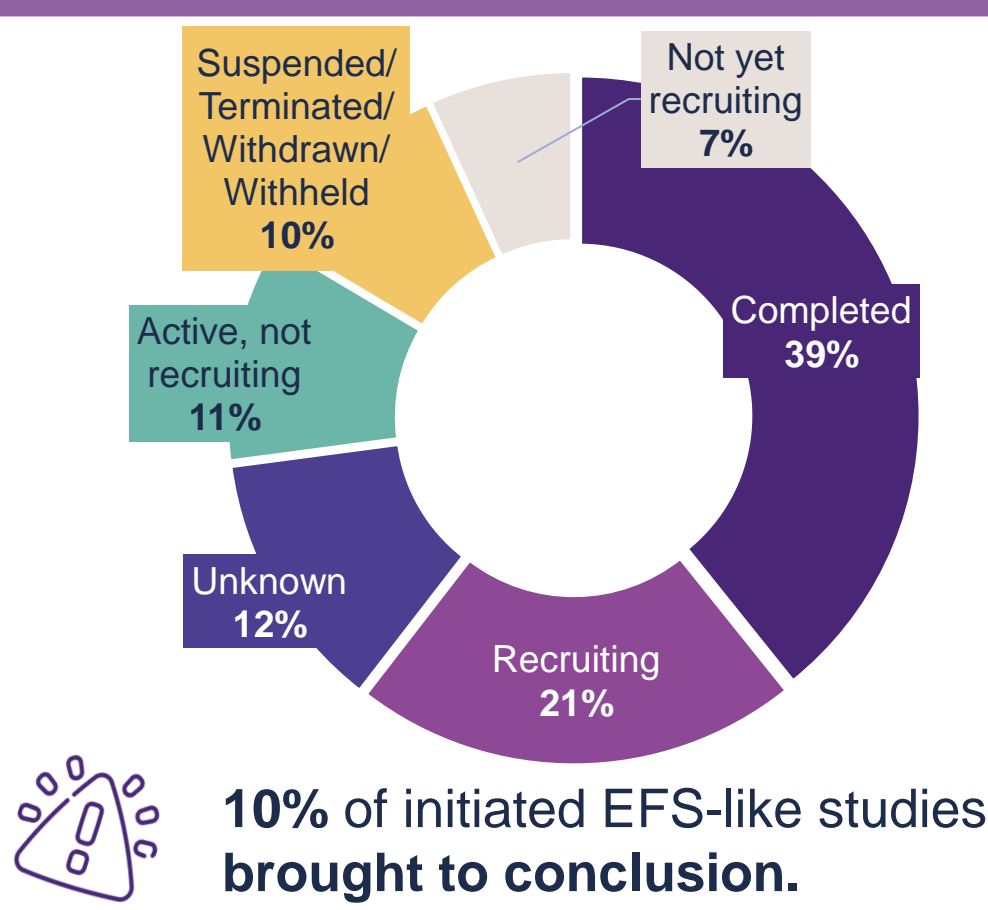
Geographic location



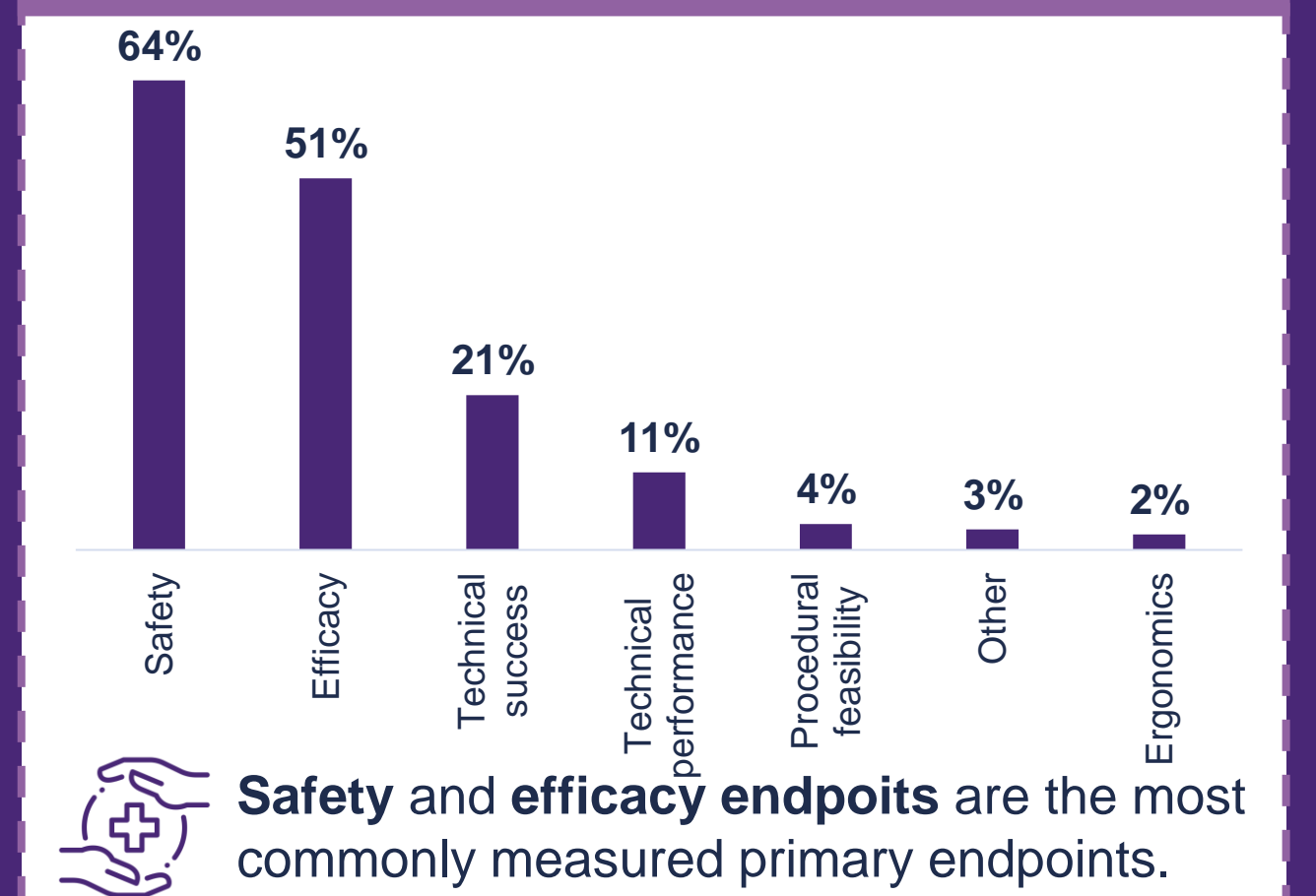
Medical conditions (ICD-10)



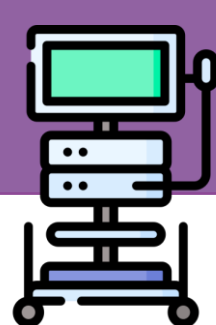
Study status



Categories of primary endpoints



## FOCUS ON CASE STUDIES



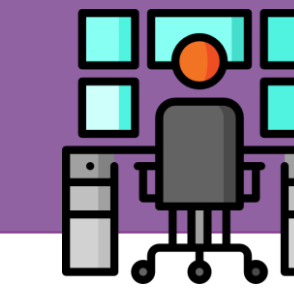
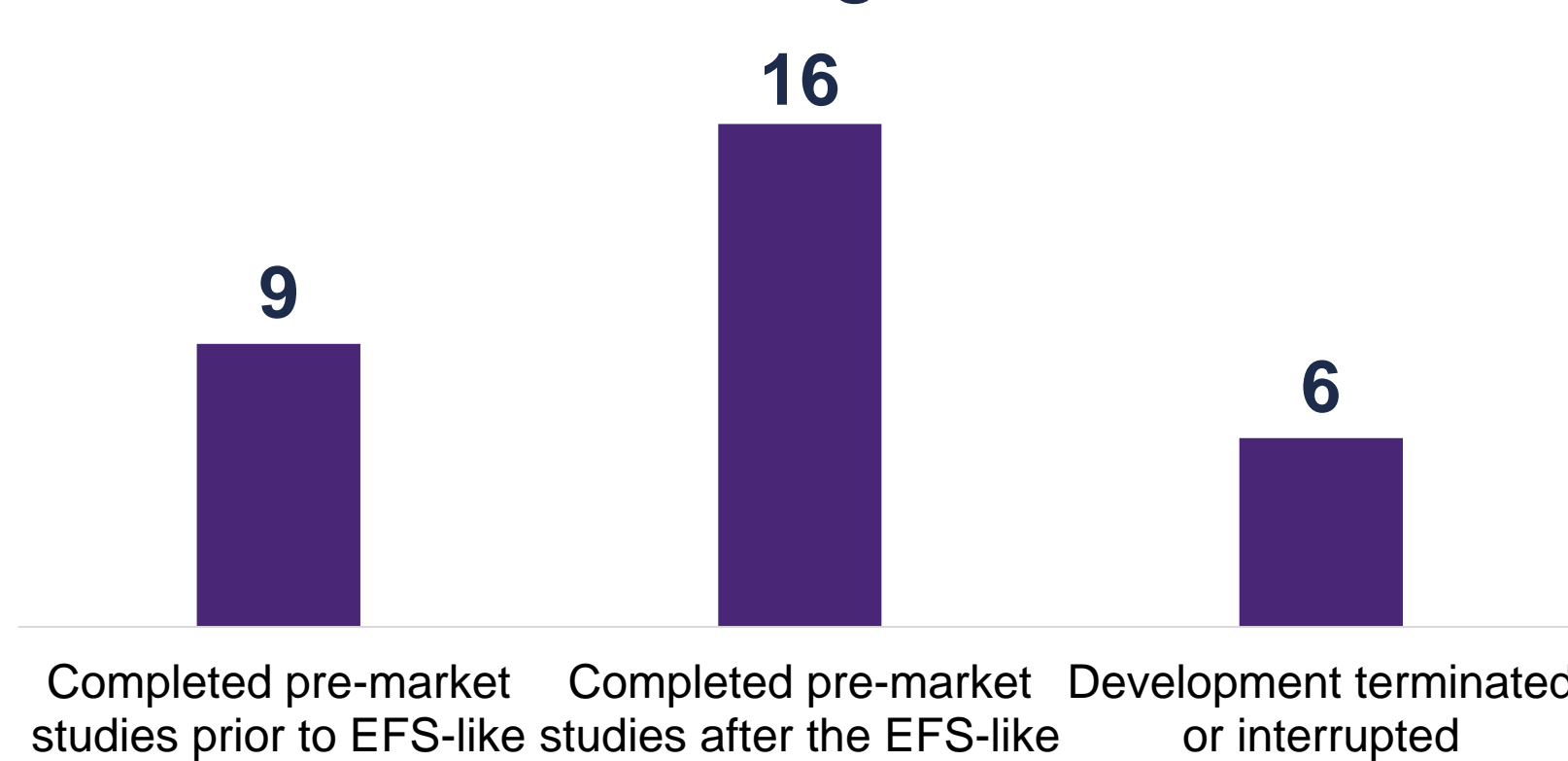
### SAMPLE CHARACTERISTICS

- 28 devices investigated
- All class III
- 17 devices investigated under EFS-FDA program



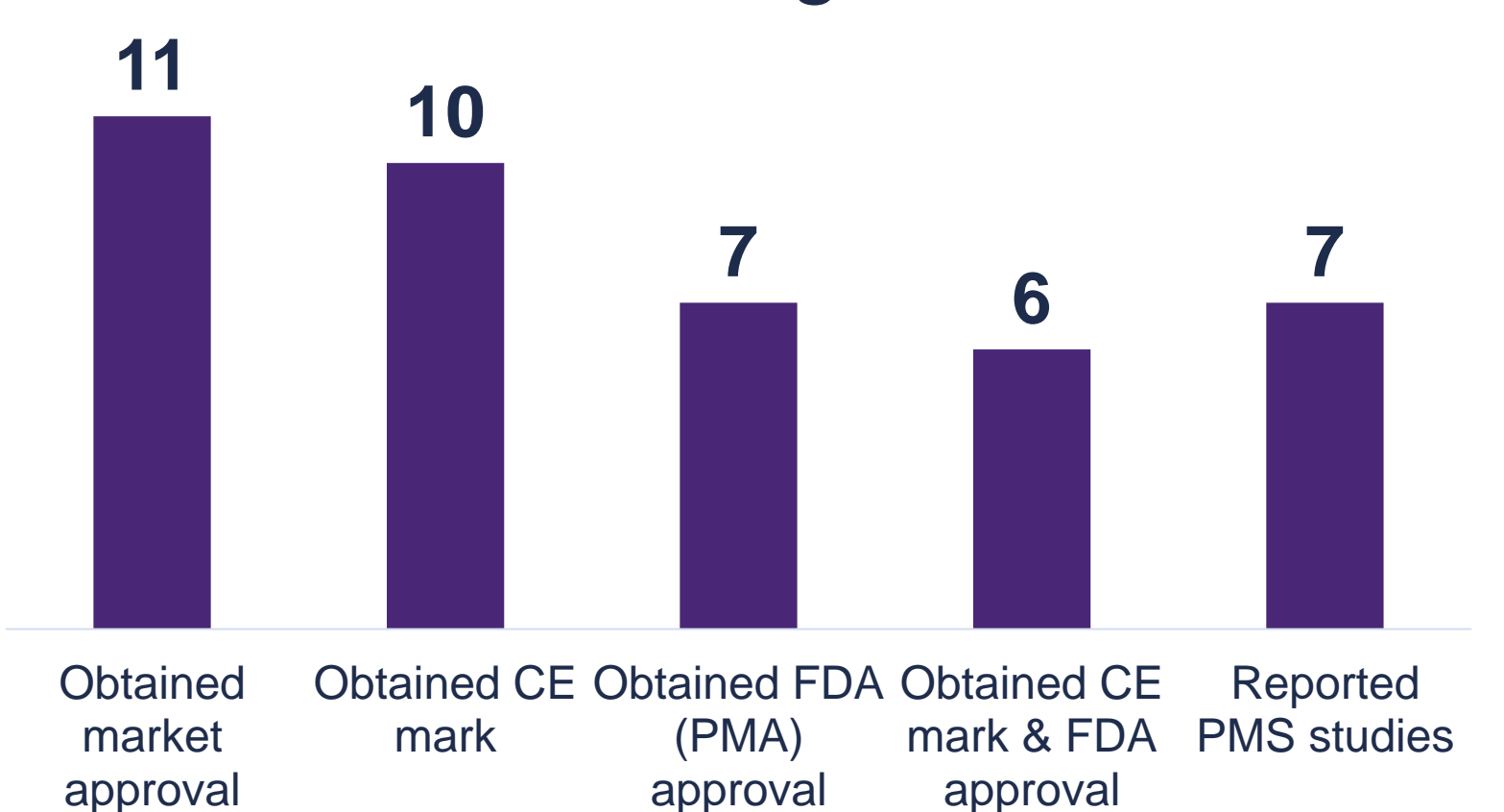
### PRE-MARKET

Out of 28 investigated devices:



### POST-MARKET

Out of 28 investigated devices:



## CONCLUSIONS

Increasing relevance of EFS both globally and in Europe



First comprehensive database created from public sources

## HELP US SHAPE THE FUTURE OF EFS IN EUROPE!

If you have any experience conducting pre-market clinical investigations of MDs, scan the QR code and answer to a brief survey.

