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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.

22 Partners

14 Advisory Board members

3 Academia	3 NCAs
4 Healthcare providers	2 Notified Bodies
2 HTA bodies	2 Ethics committees
2 Patient organizations	4 Professional associations
1 CRO	1 Network
2 SMEs	1 Trade Association
6 Private consortium	1 Independent expert

13 Countries involved: 9 EU (BE, DE, DK, ES, FR, IE, IT, NL, PT), 1 EEA (NO), 3 non-EU (UK, CH, US).

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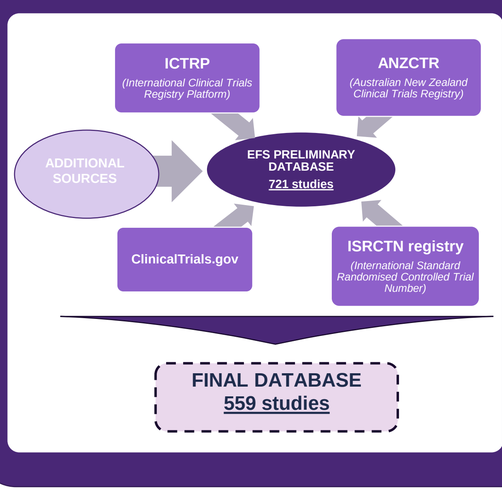
INTRODUCTION & OBJECTIVE

- **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

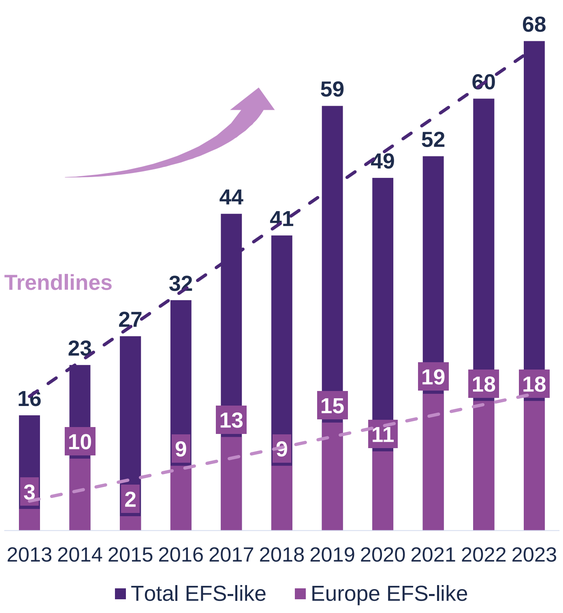
1. **EFS: description** in title or summary of the study as **«early feasibility»** or **«EFS»** OR
2. **EFS-like:**
   - Study type: **Interventional**;
   - Estimated sample size **<= 30**;
   - **Non-randomized** allocation
   - Interventional mode: **single group assignment**;
   - Masking: **None**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

2. **Survey** on EFS sponsored by Consortium Partners.

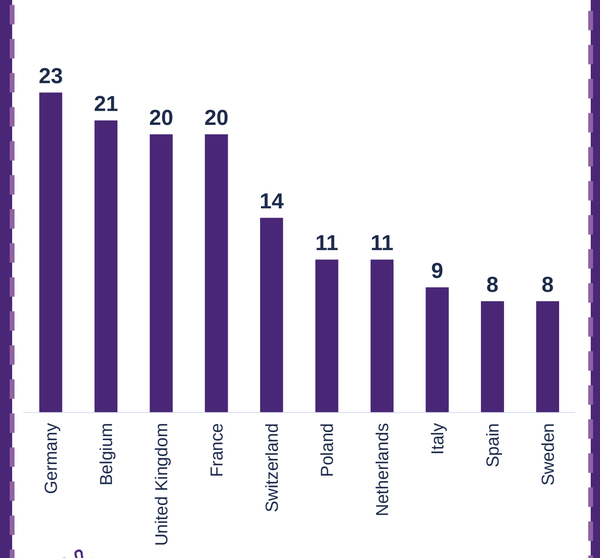
1-to-1 interviews to validate and integrate results.

RESULTS

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

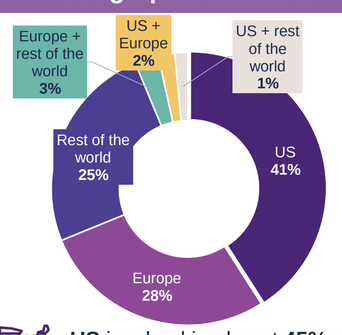


EFS-like studies in Europe 2013-2023



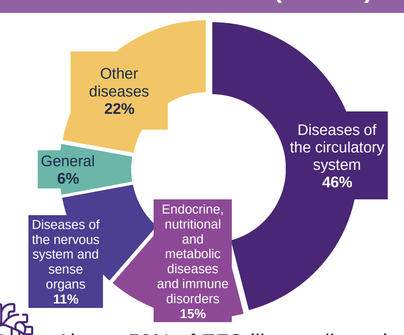
Multi-country studies are reported once for each location

Geographic location



US involved in almost **45%** of EFS-like studies.

Medical conditions (ICD-10)

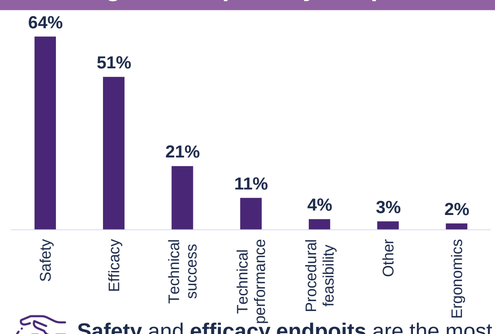


Almost 50% of EFS-like studies relate to **circulatory system's diseases**

Study status

10% of initiated EFS-like studies is **not brought to conclusion.**

Categories of primary endpoints



Safety and **efficacy endpoits** are the most commonly measured primary endpoints.

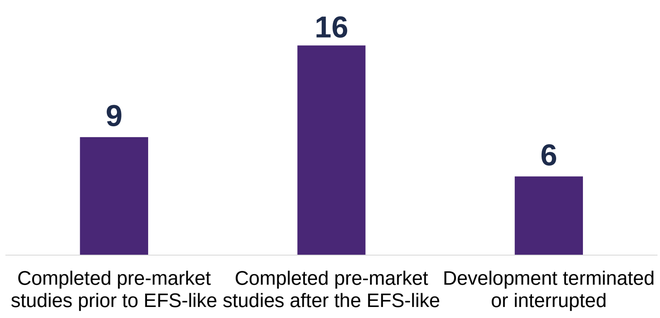
FOCUS ON CASE STUDIES

SAMPLE CHARACTERISTICS

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

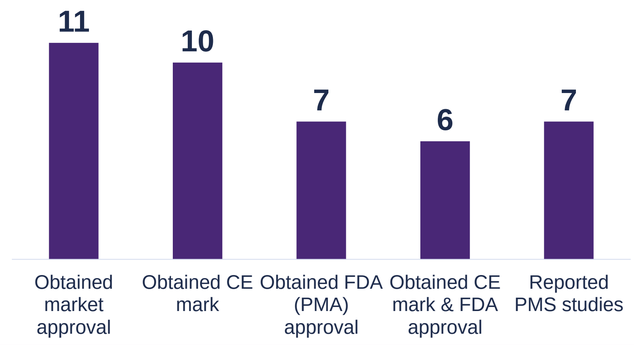
PRE-MARKET

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.

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