

Overview of numbers in Belgium (and in Europe) for CTR early trials

Federal Agency for Medicines and Health Products (FAMHP)

15.09.2023

Hans VINCKE

Agenda

Introduction

Numbers 1st year of CTR (31/01/2022 – 30/01/2023)

Numbers 2nd year of CTR, 1st half (31/01/2023 – 31/07/2023)

Disclaimer:

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Introduction

- Clinical Trials Regulation (CTR) into application on 31 January 2022
- Start of three-year transition period:
 - 1st year (31/01/2022-30/01/2023): choice to apply for a new clinical trial under Clinical Trials Directive (CTD) or CTR
 - From 31 January 2023: all initial clinical trial applications to be submitted under CTR via Clinical Trials Information System (CTIS)
 - Clinical trials approved under CTD can continue under CTD until 30 January 2025
 - Mandatory transition from CTD to CTR for clinical trials under CTD not expected to end before 31 January 2025
 - Transition from CTD to CTR possible for all clinical trials under CTD during entire transition period



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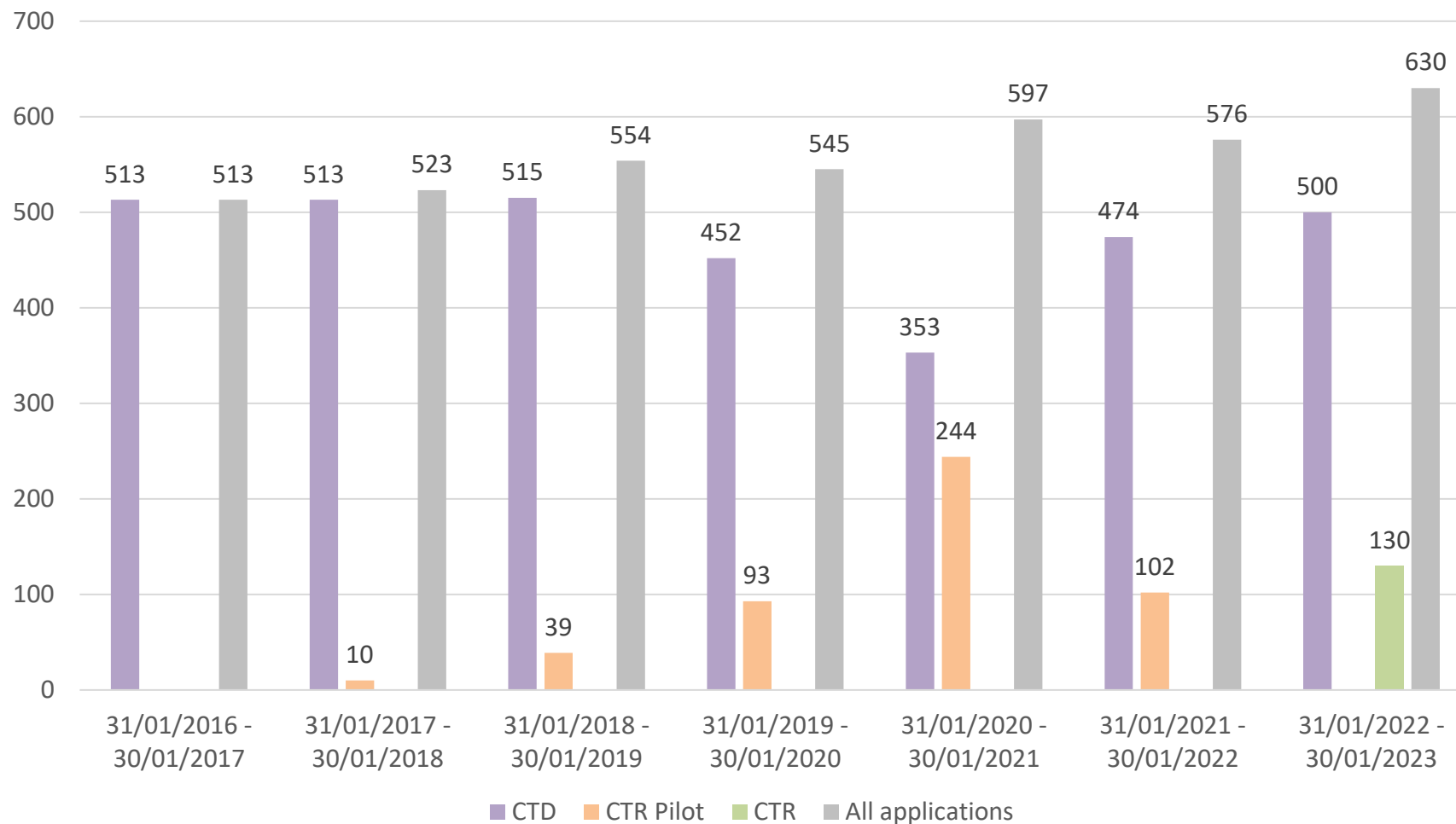
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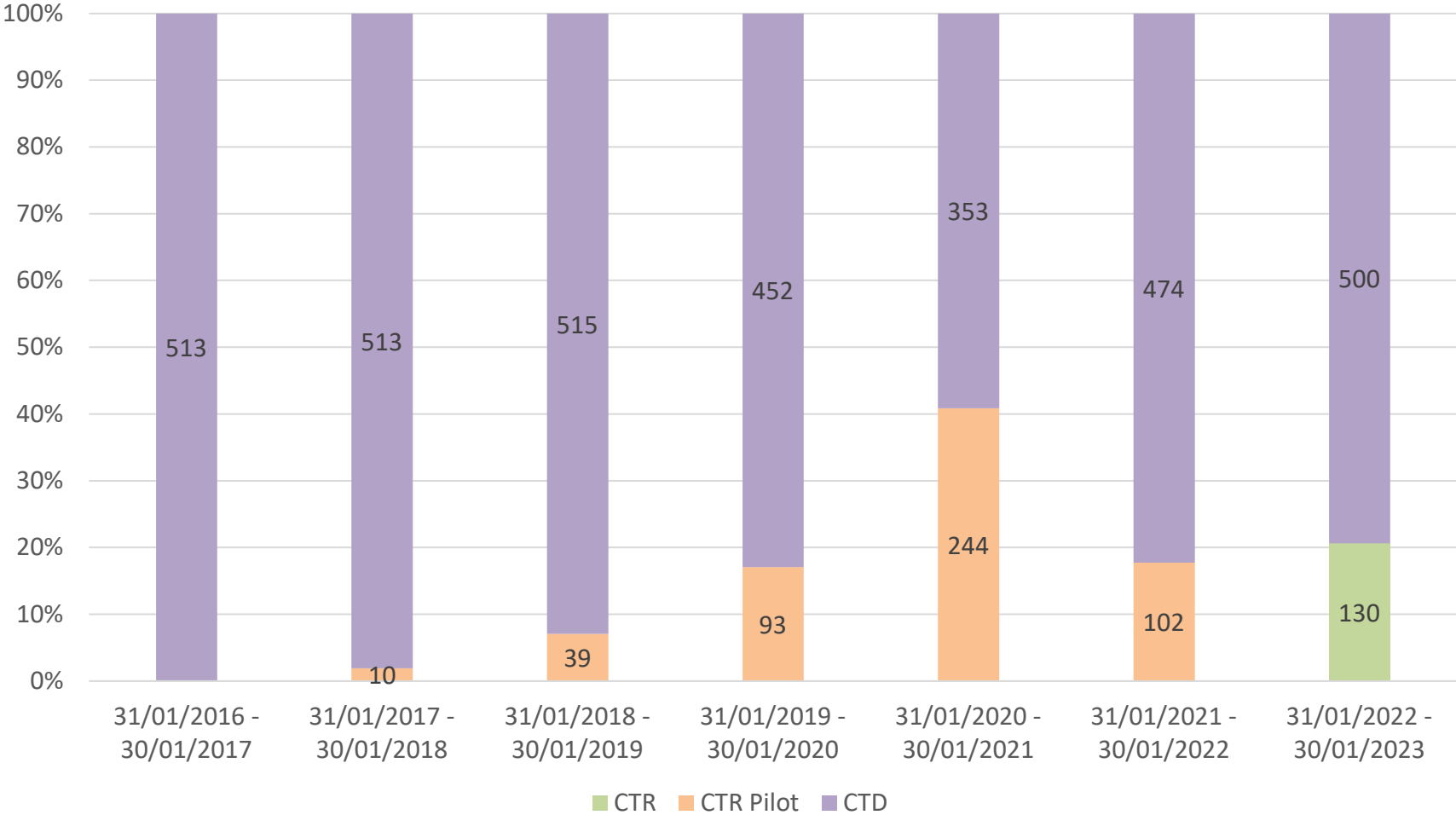
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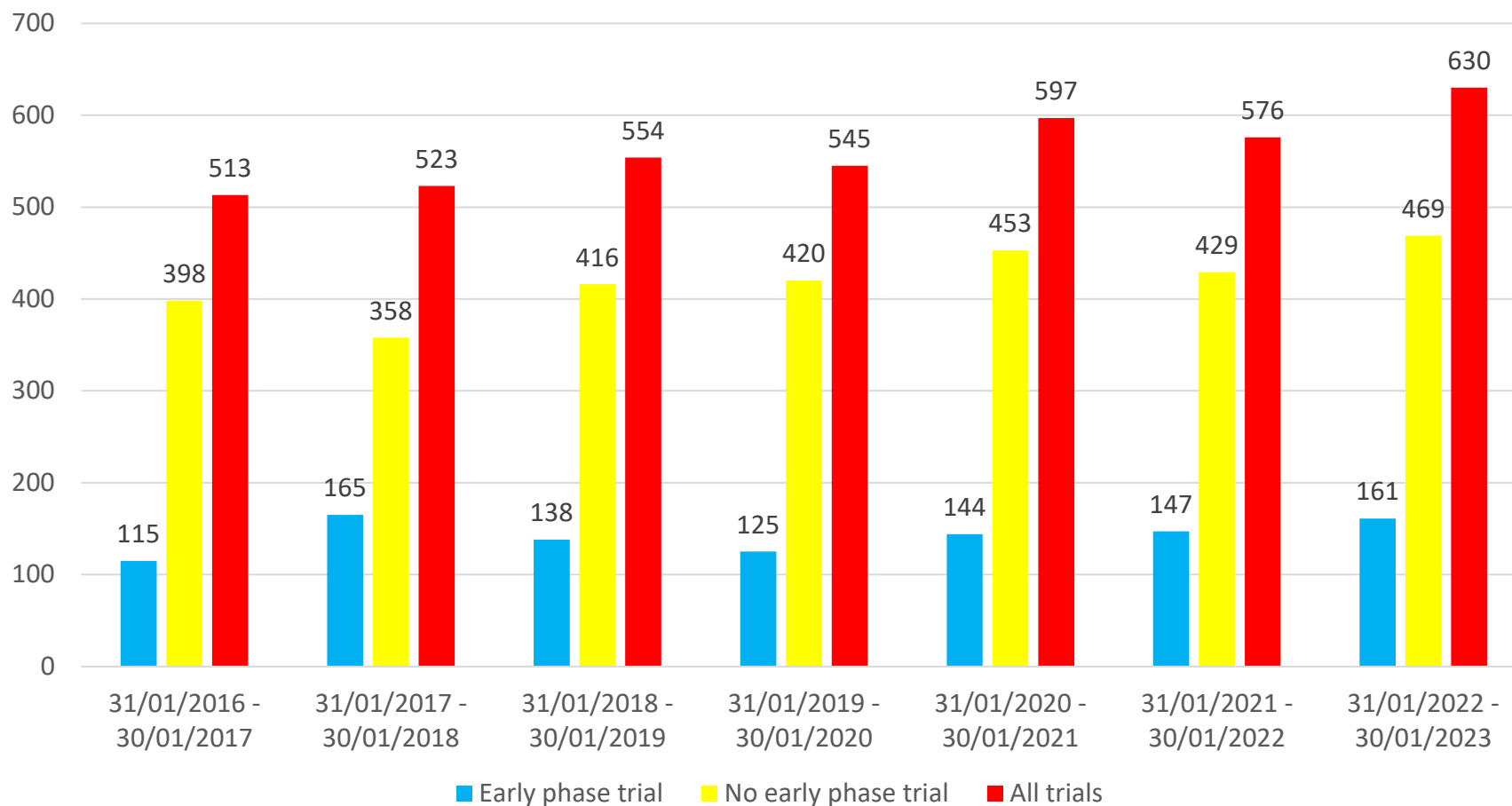
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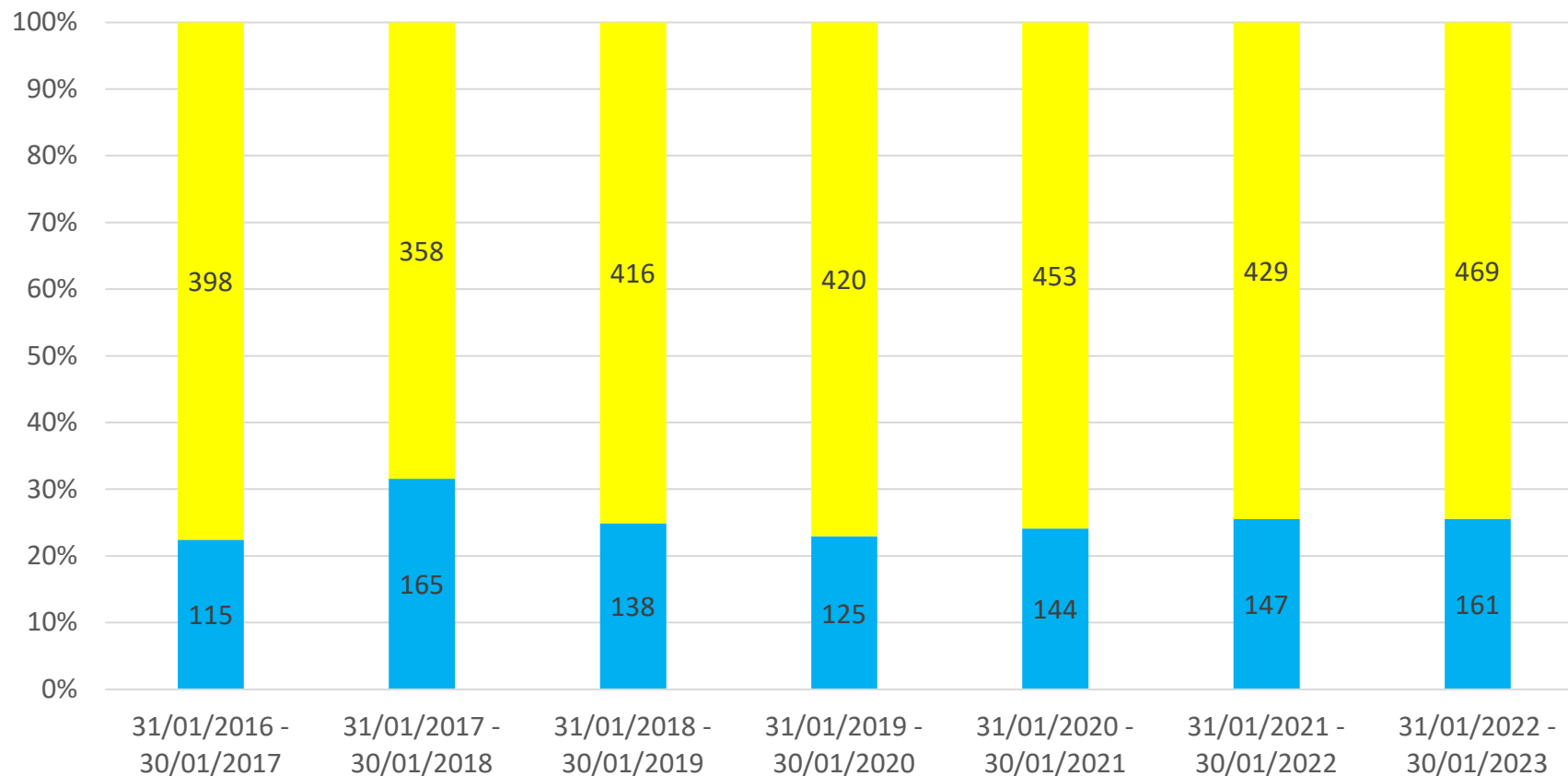
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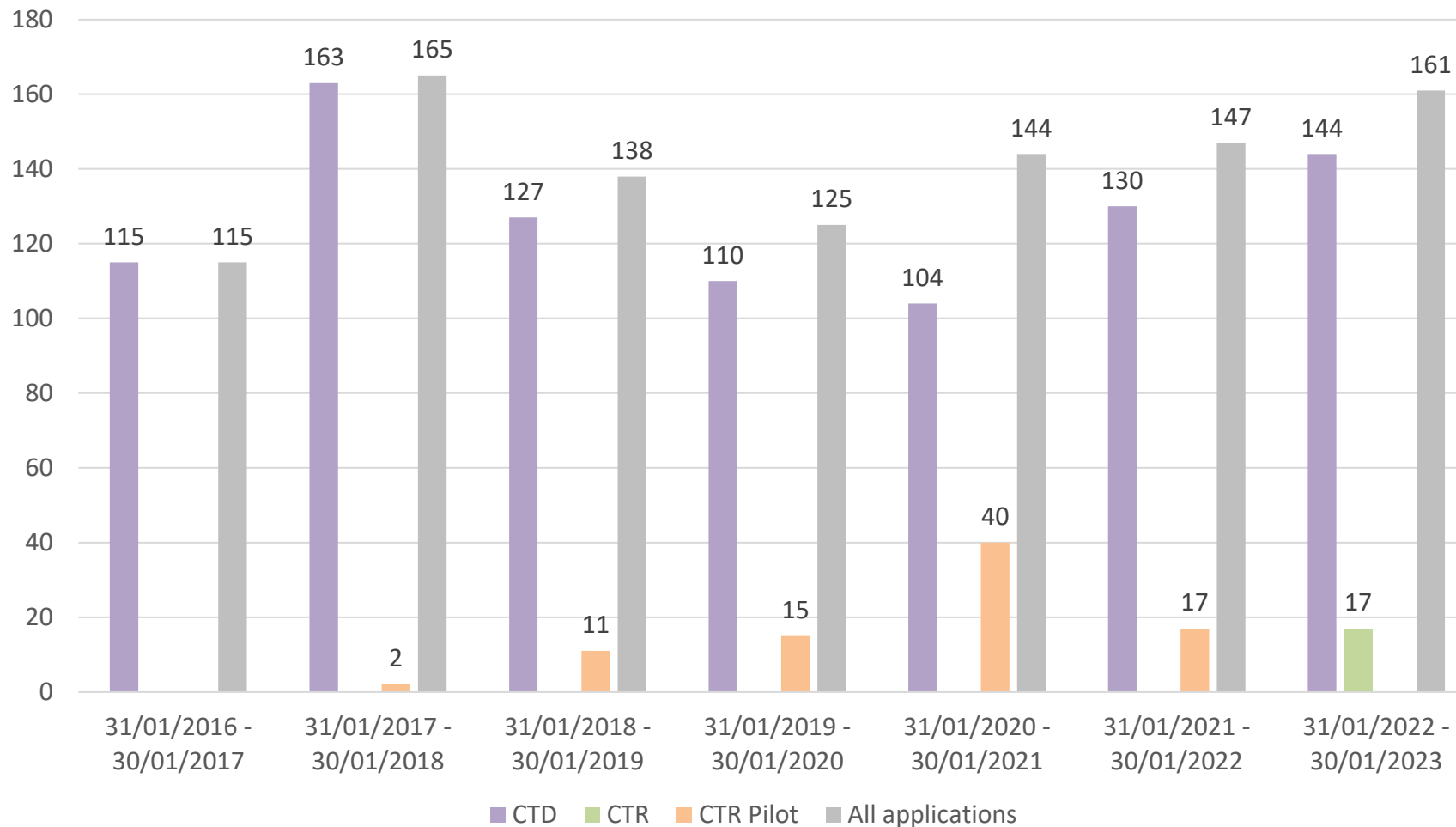
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■ Early phase trial ■ No early phase trial

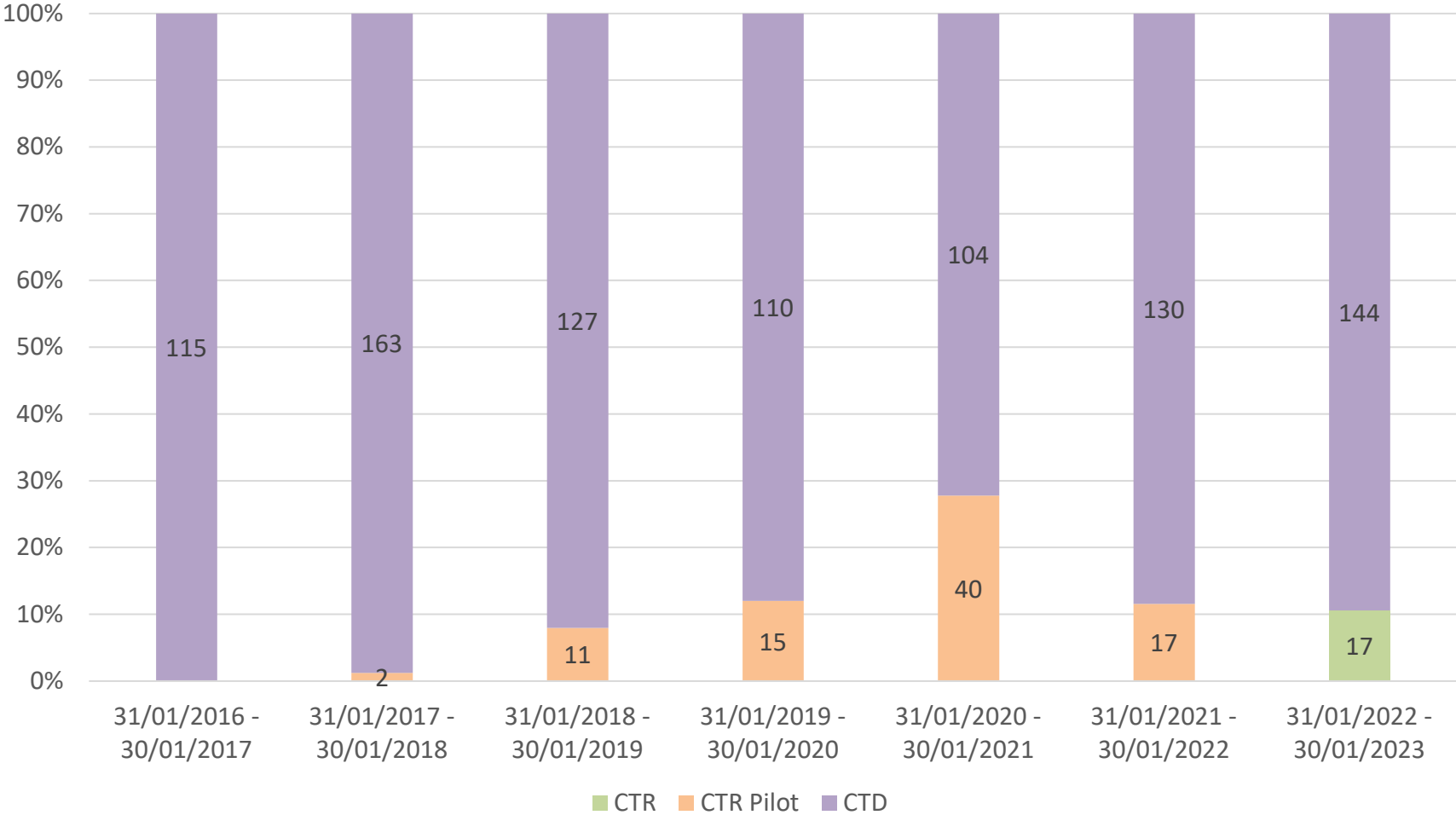
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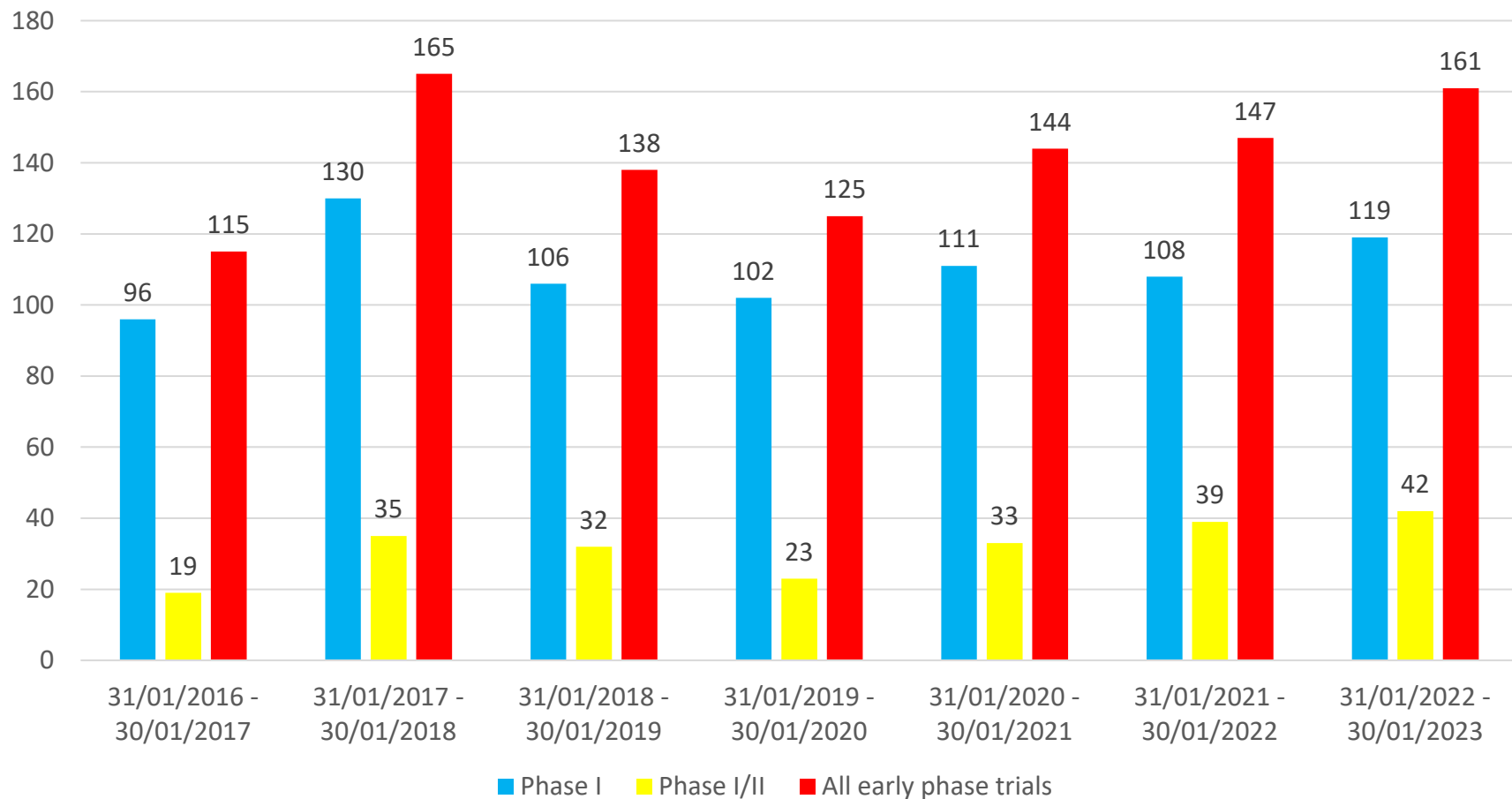
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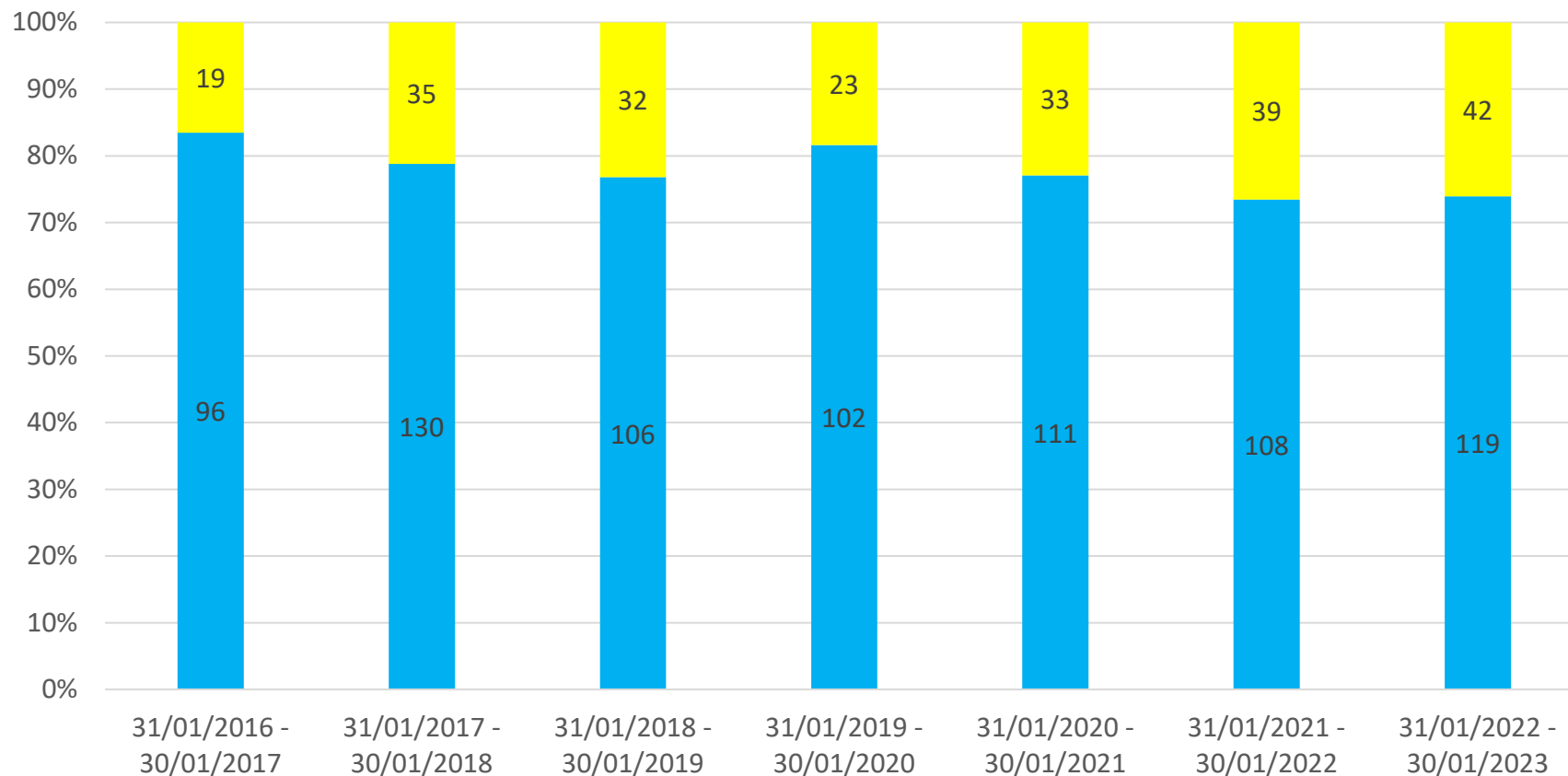
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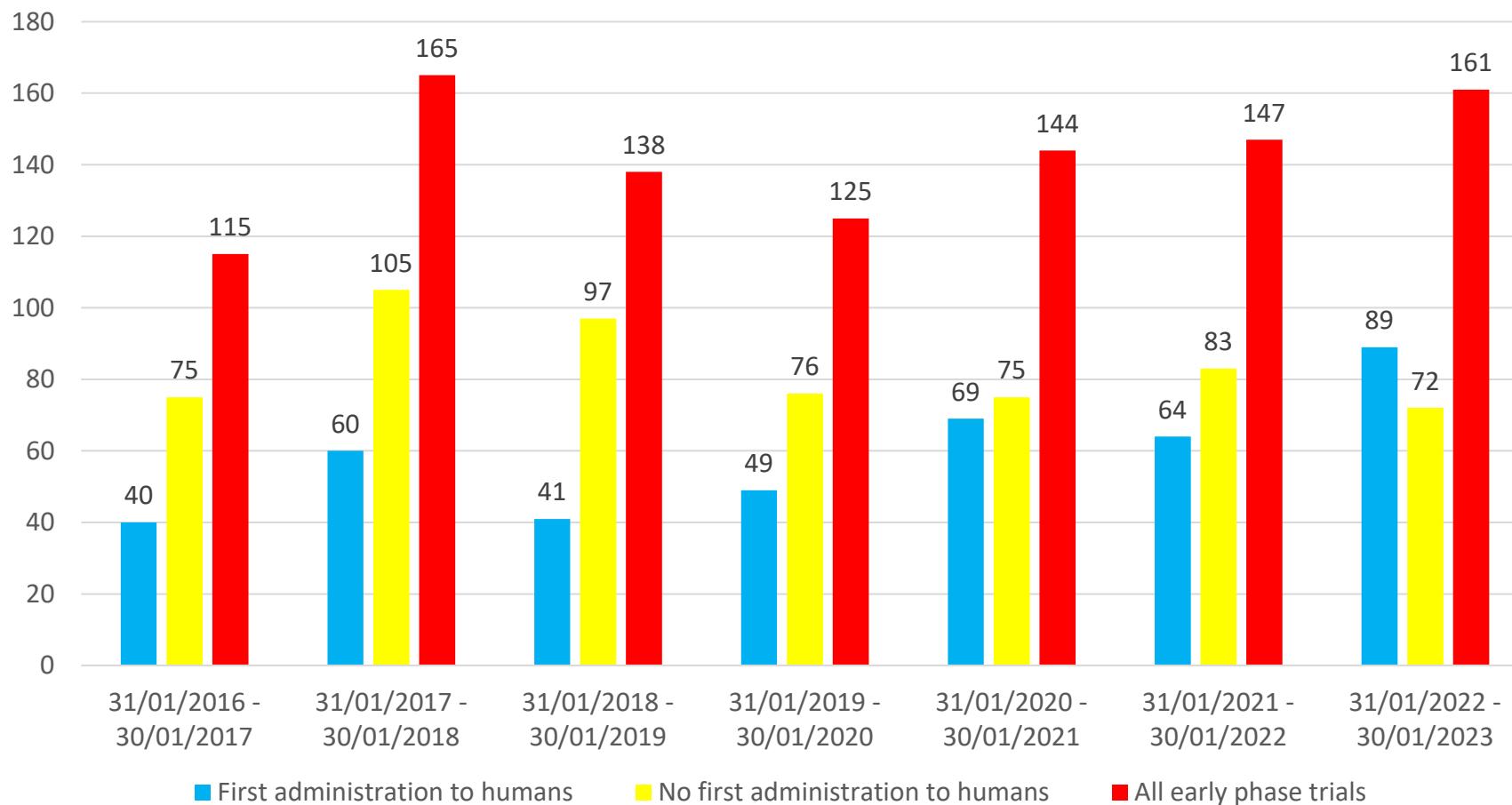
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■ Phase I ■ Phase I/II

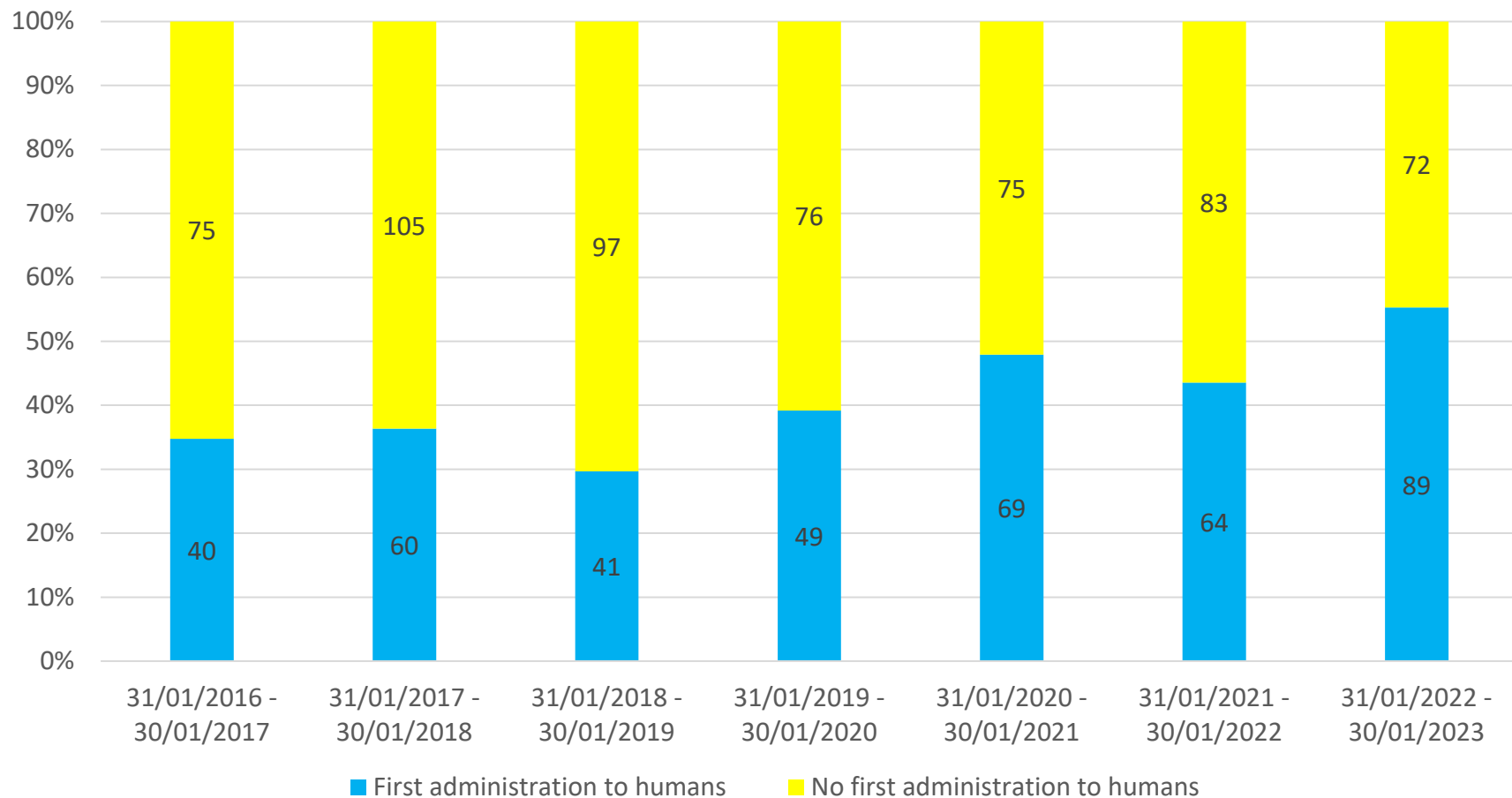
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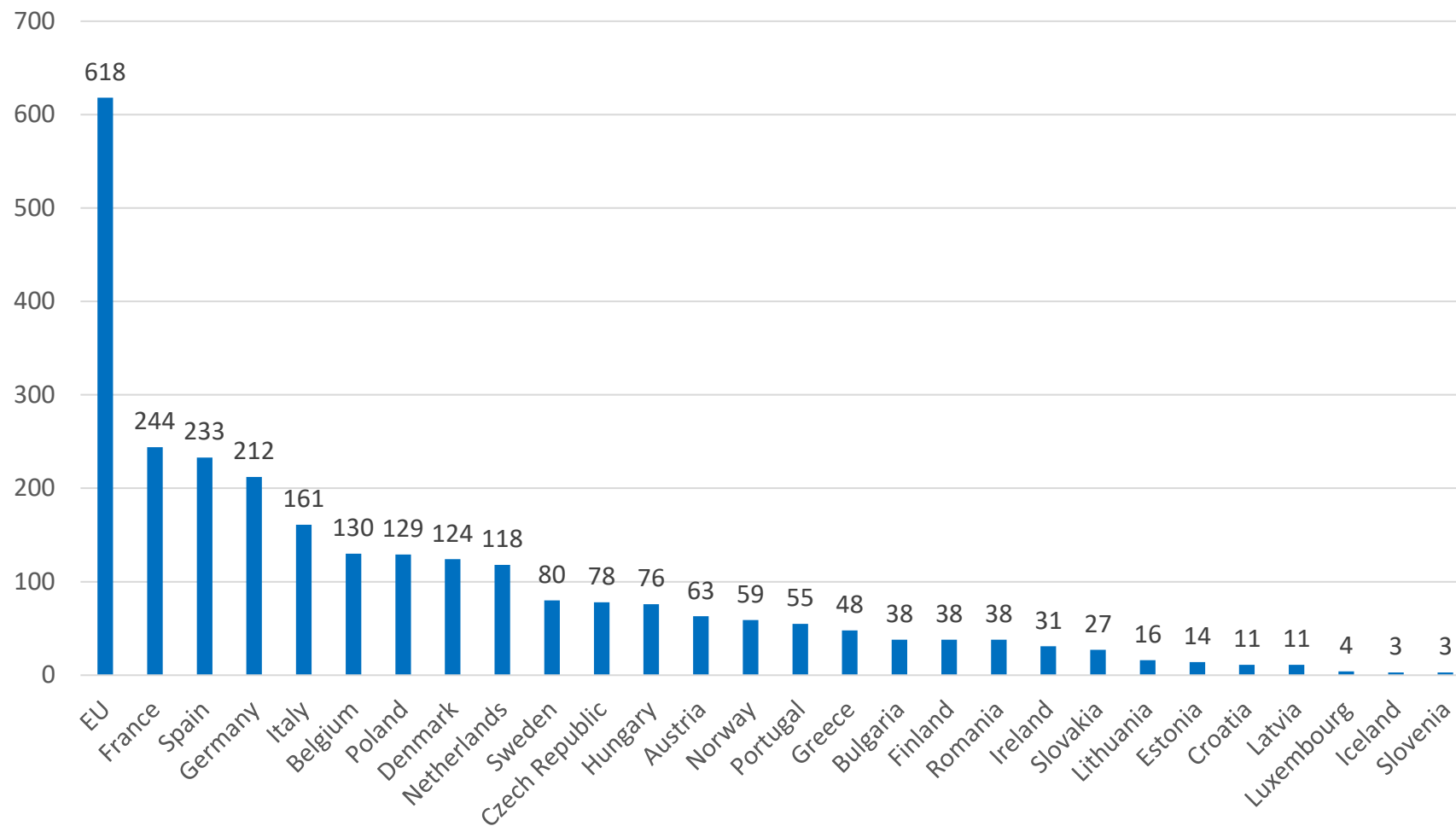
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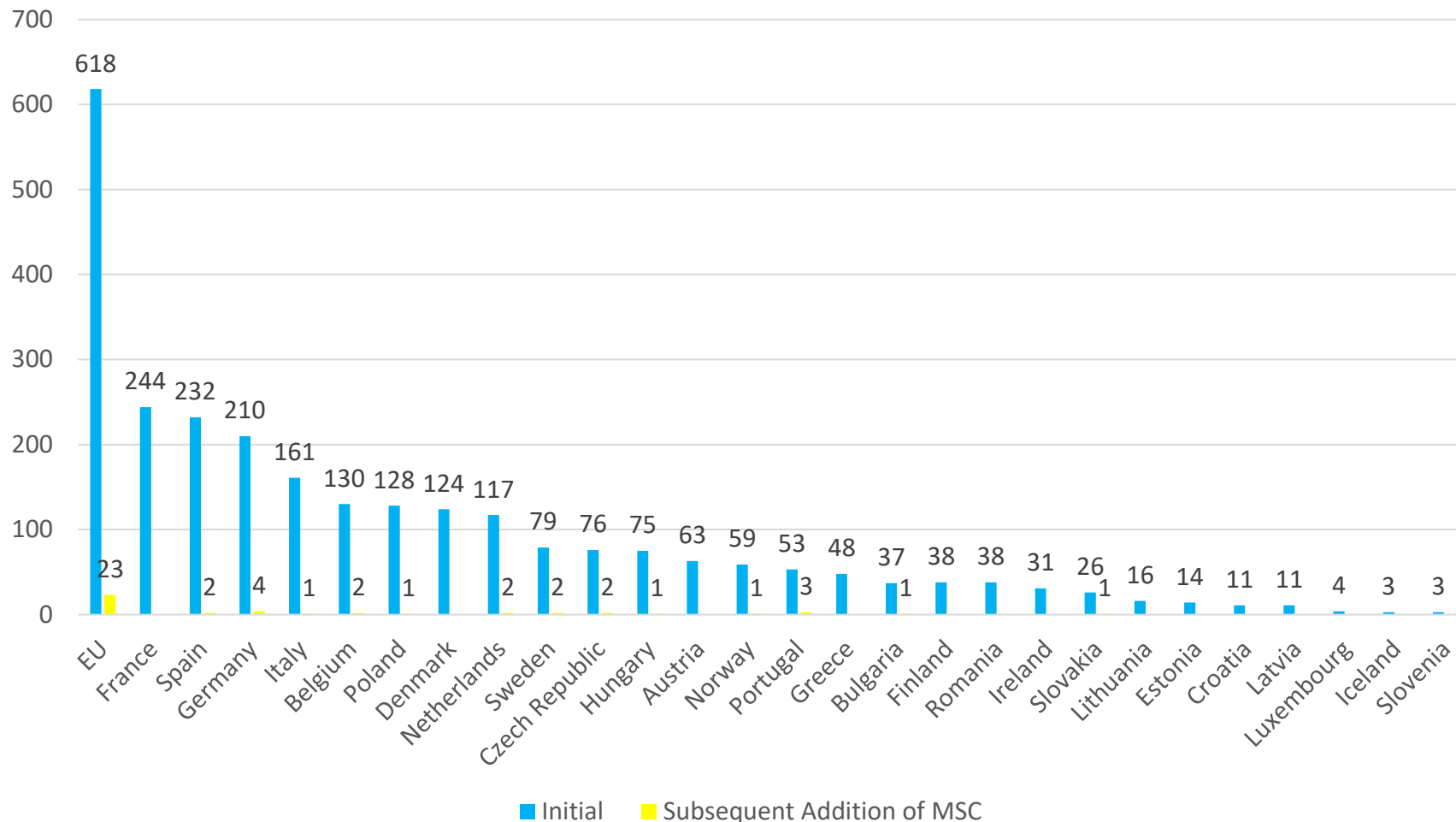
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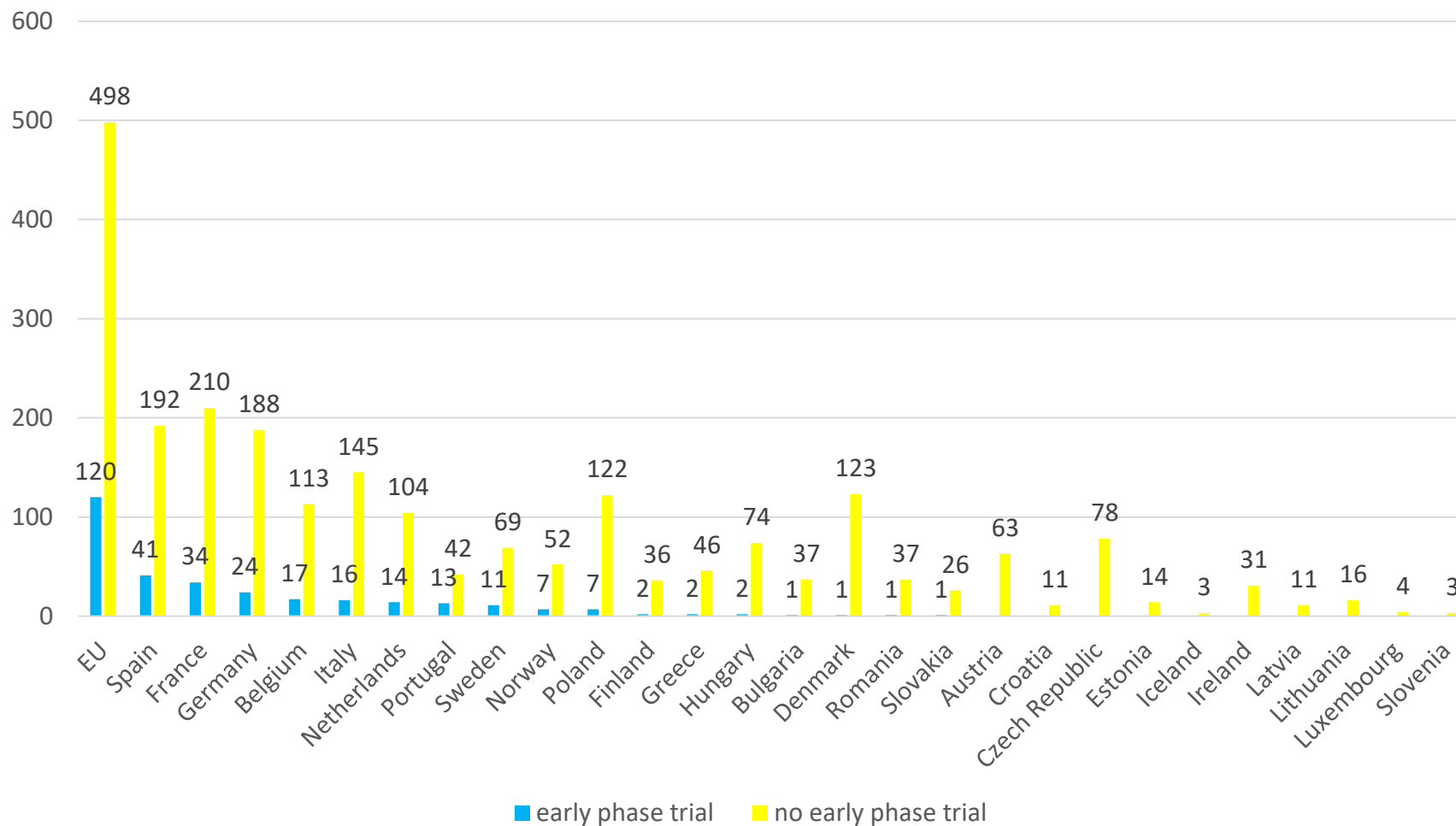
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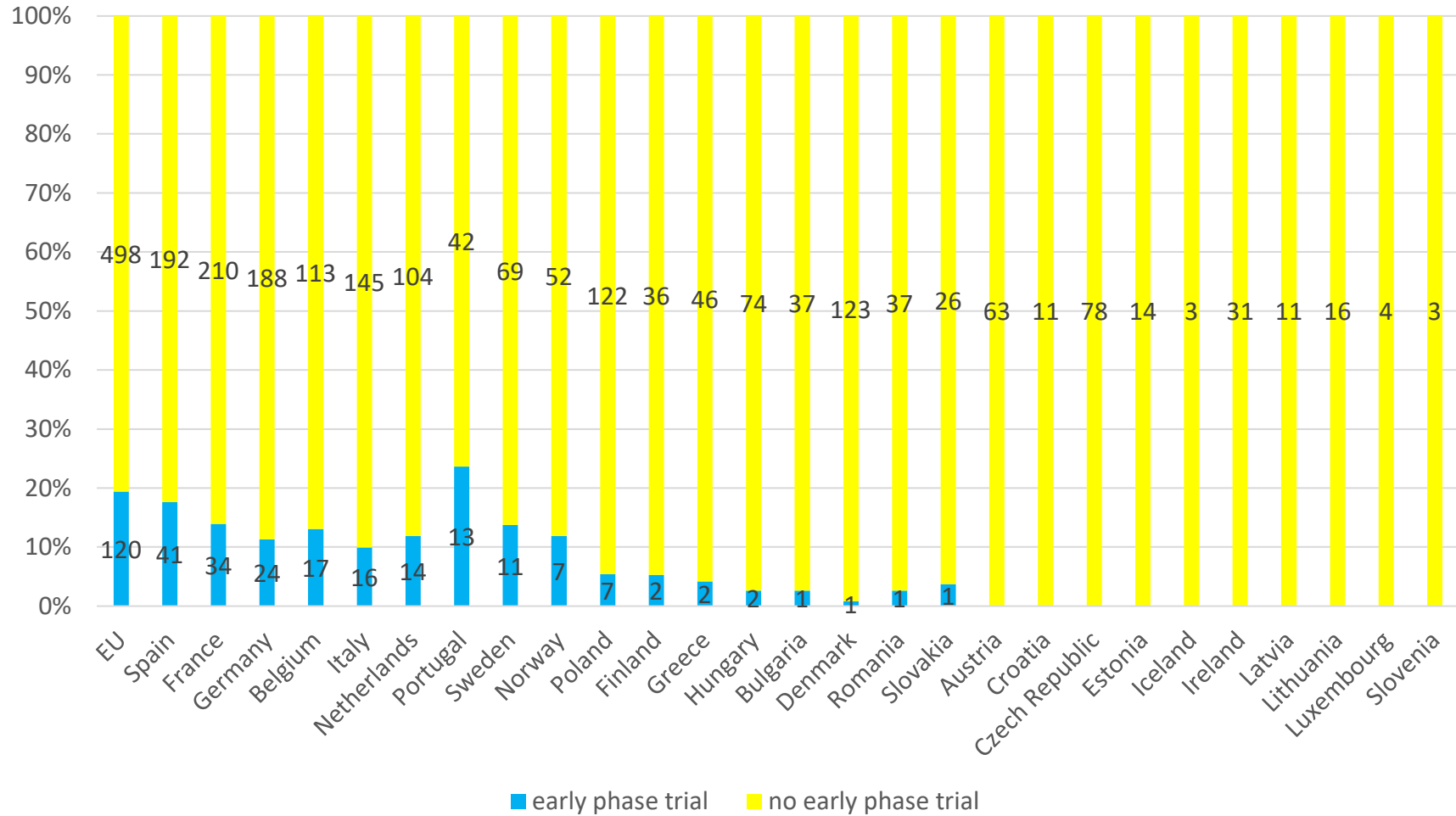
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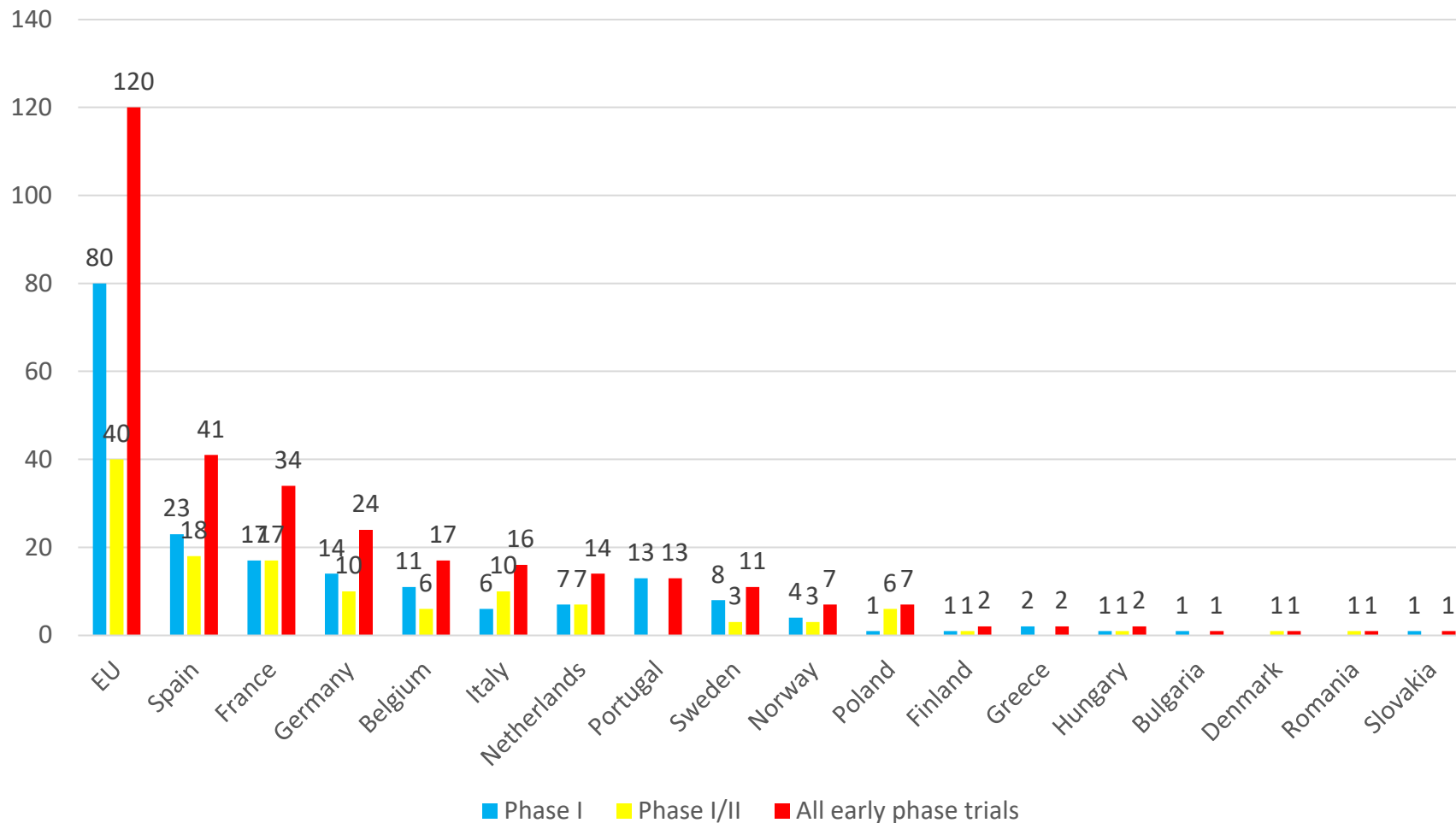
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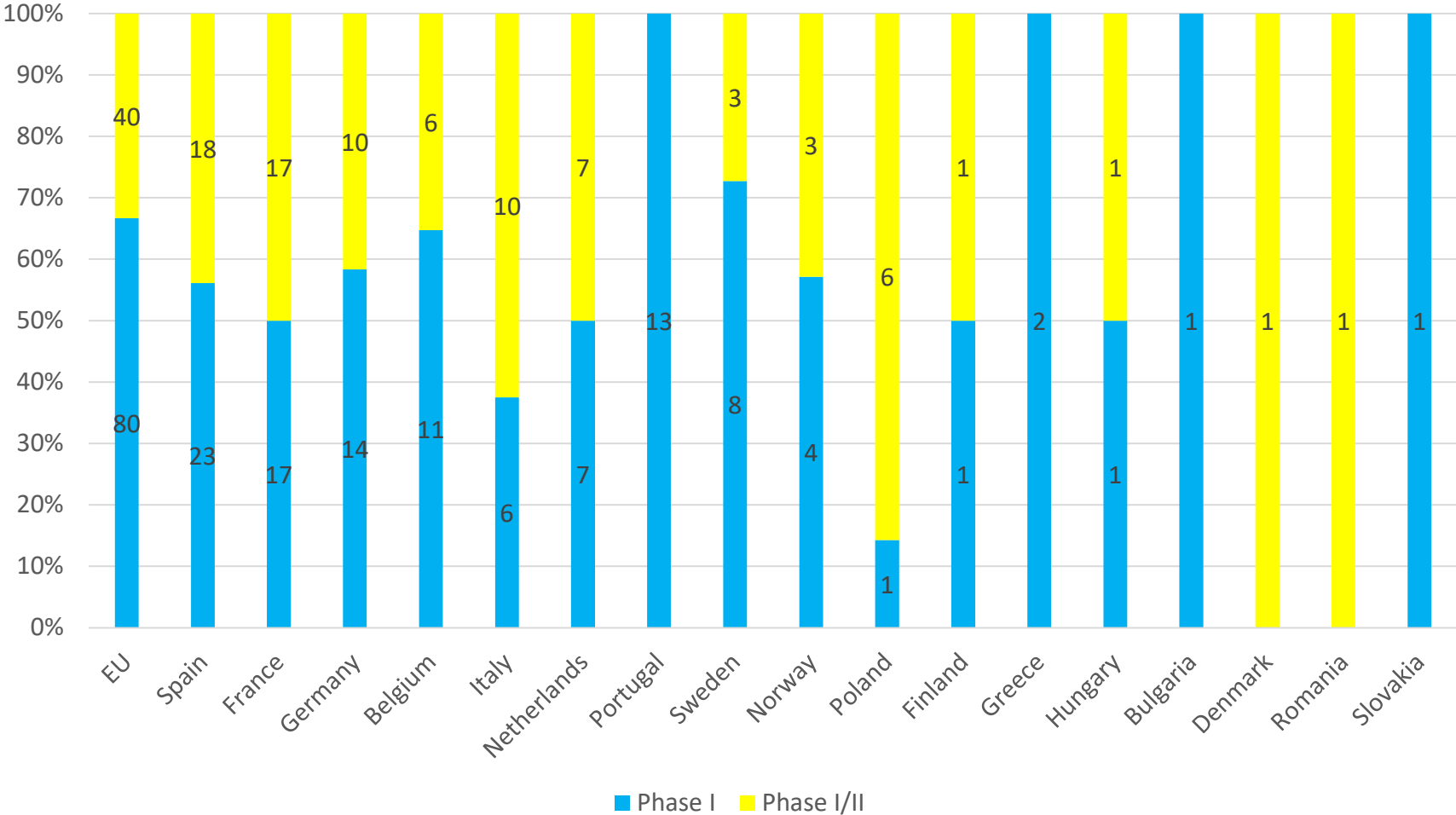
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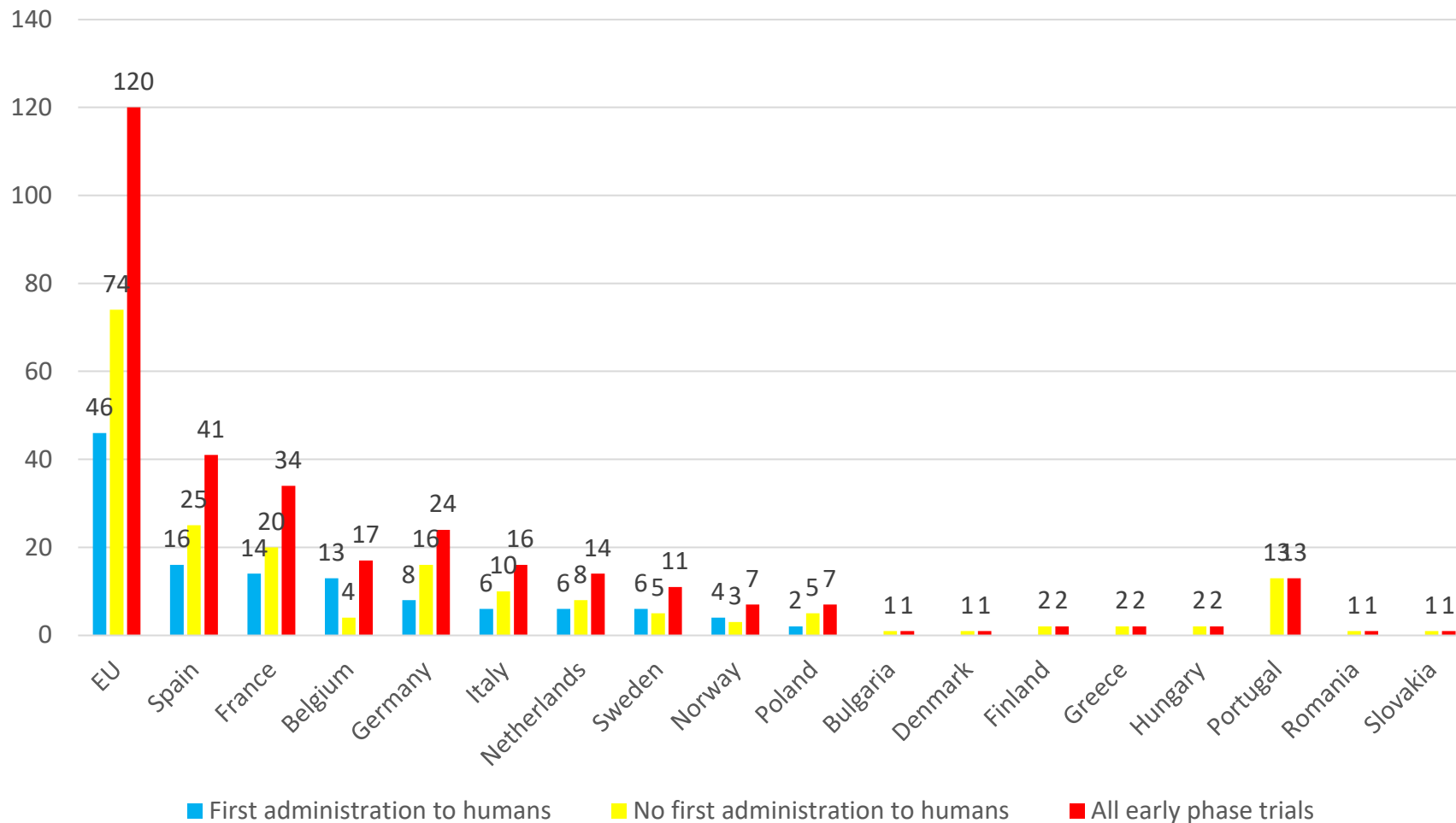
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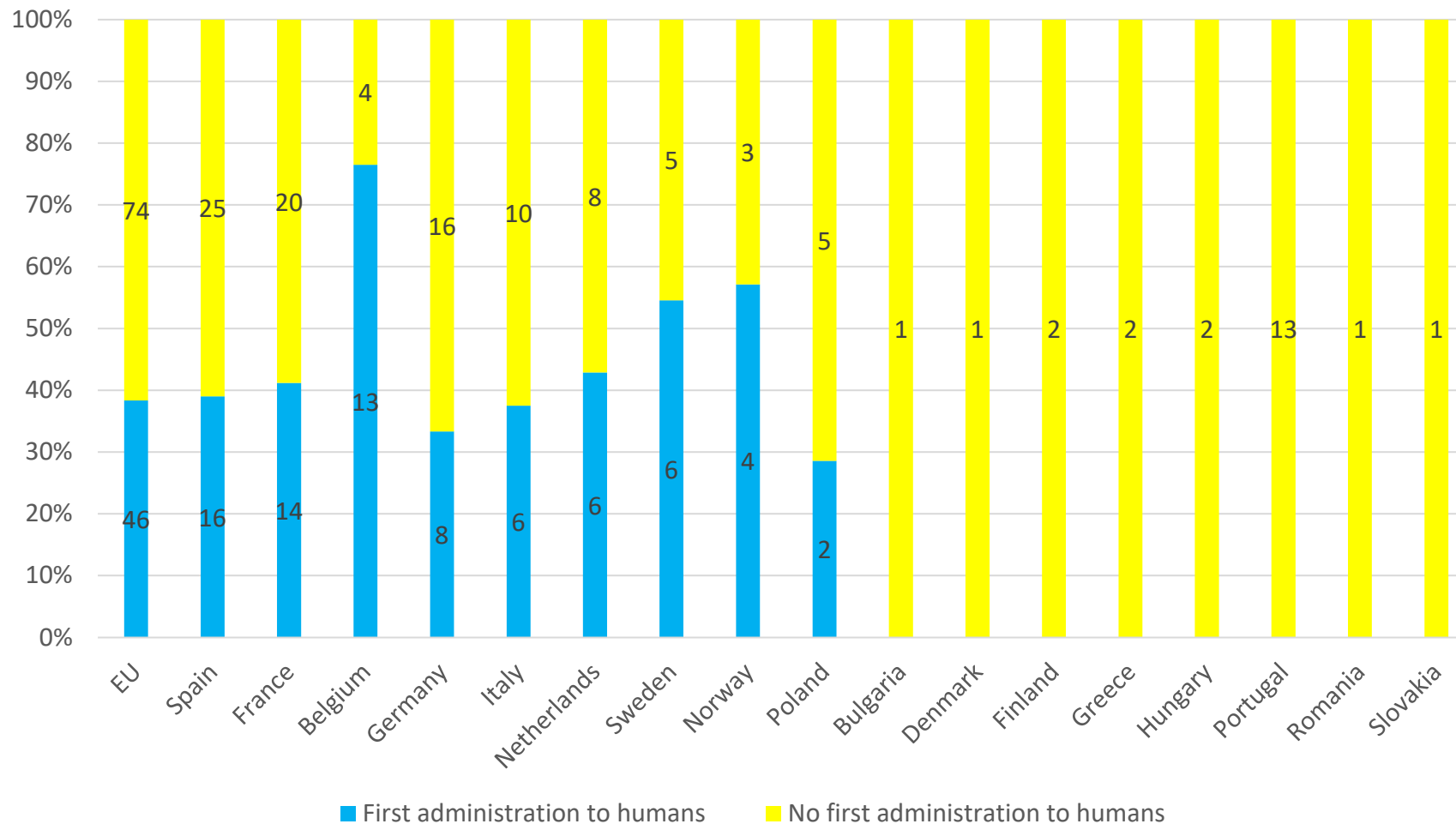
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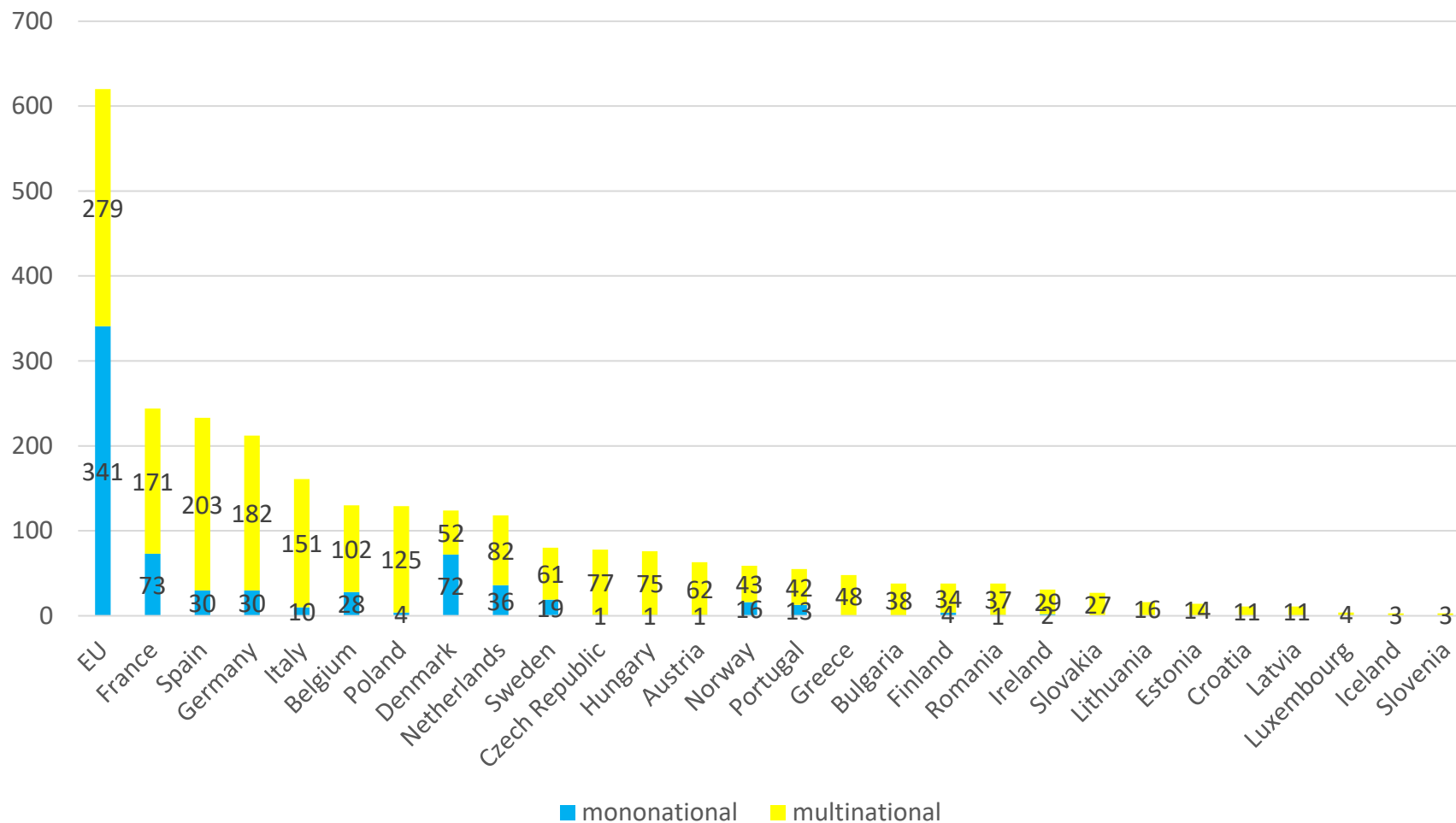
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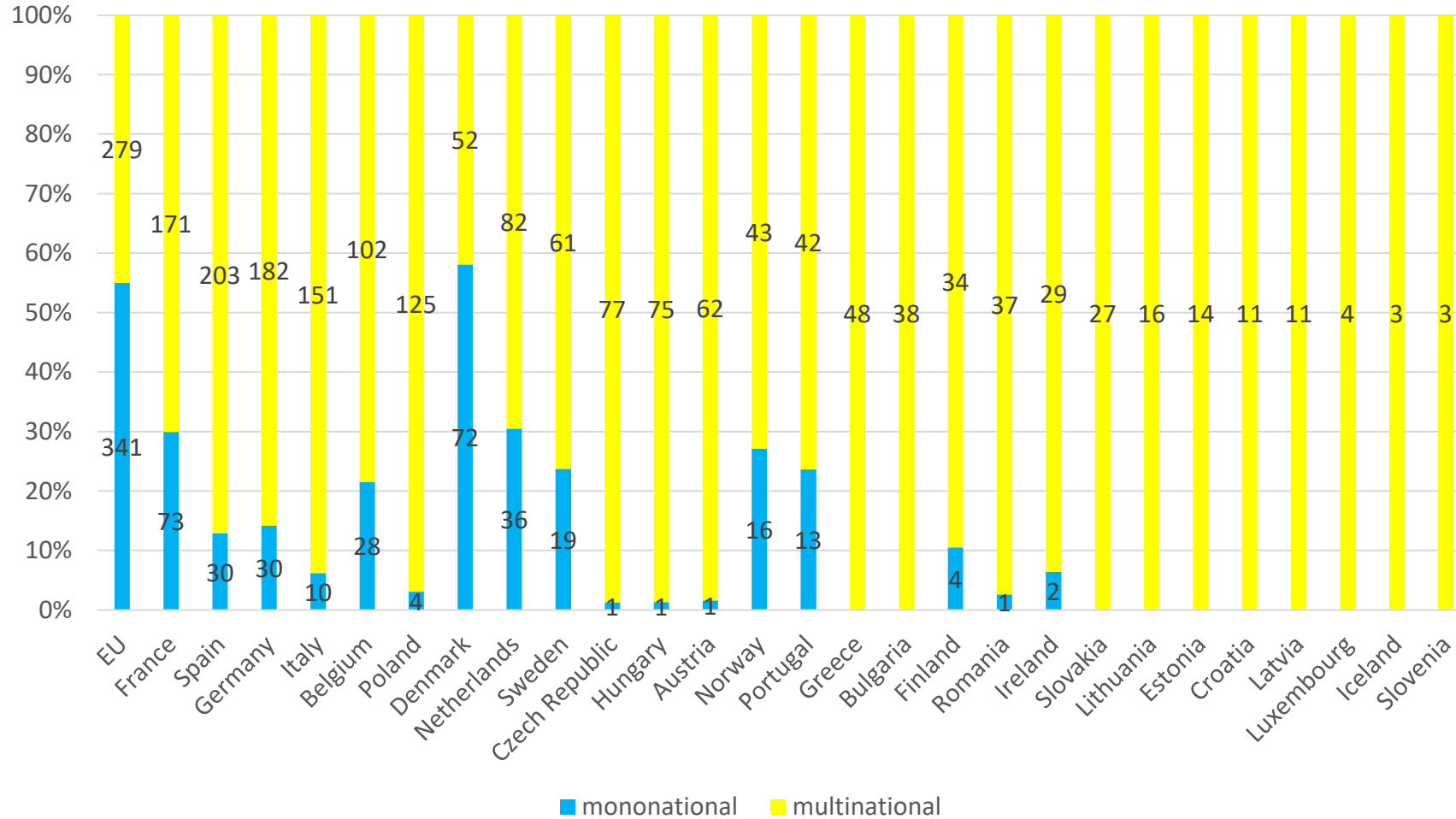
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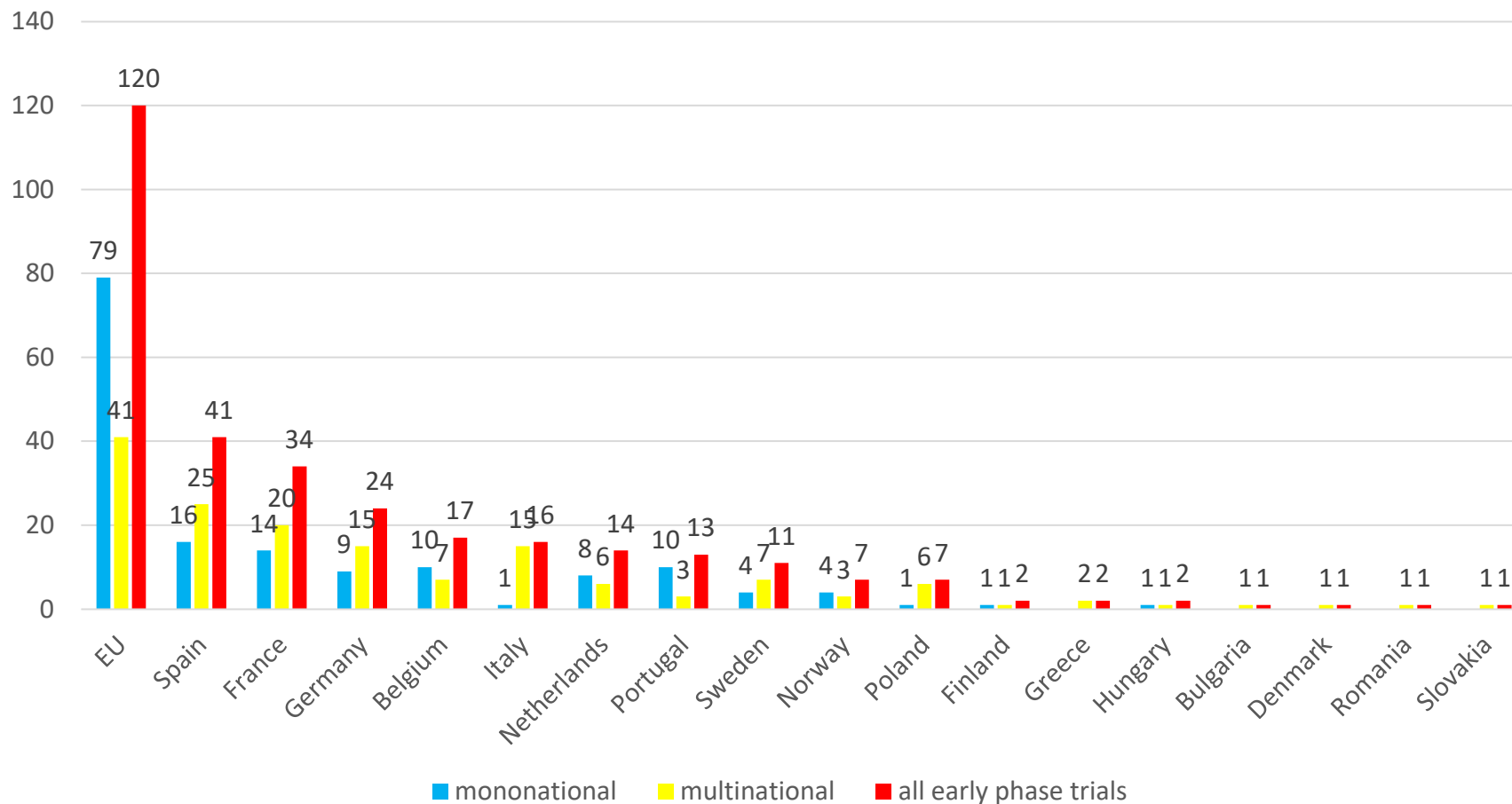
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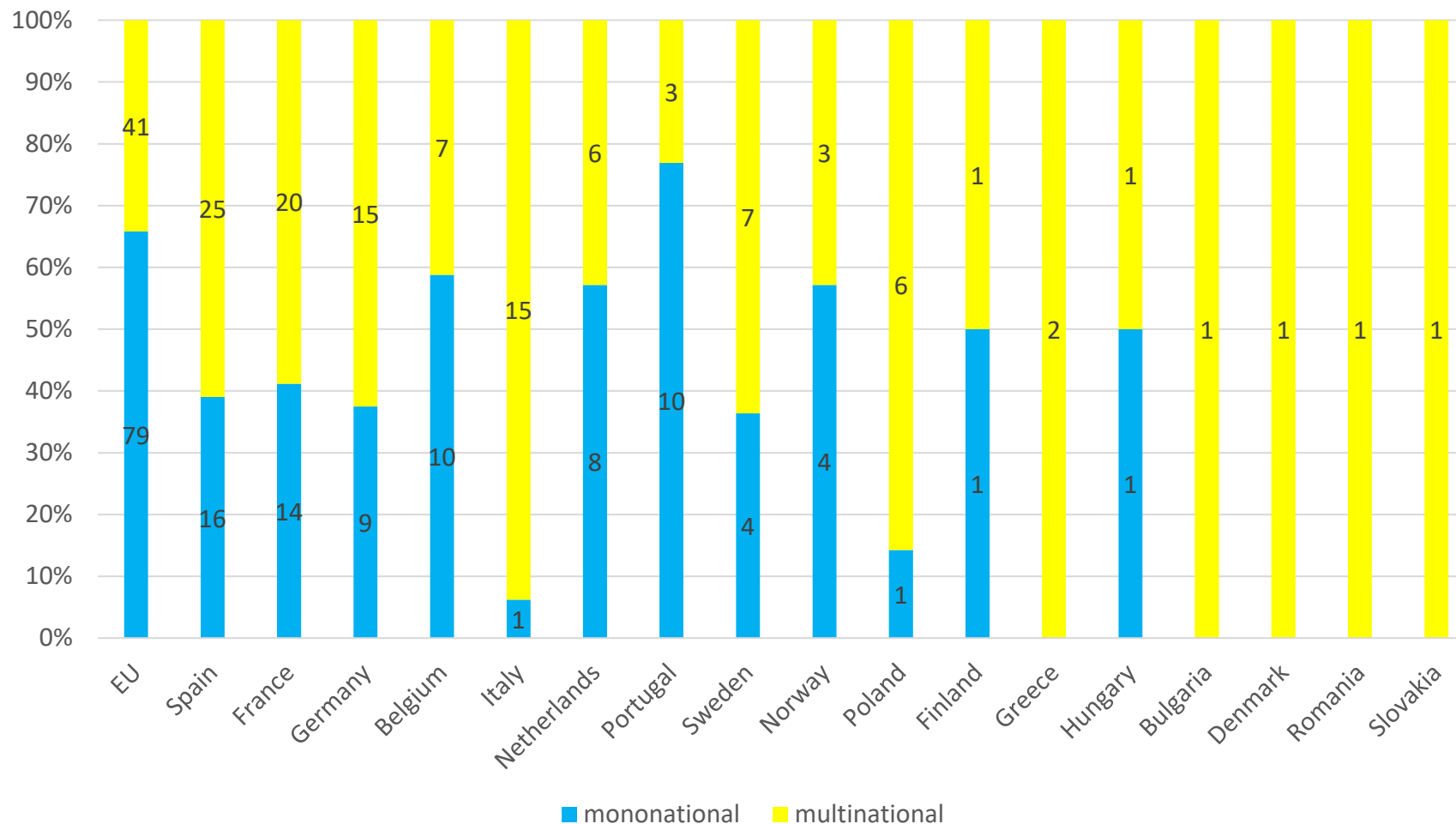
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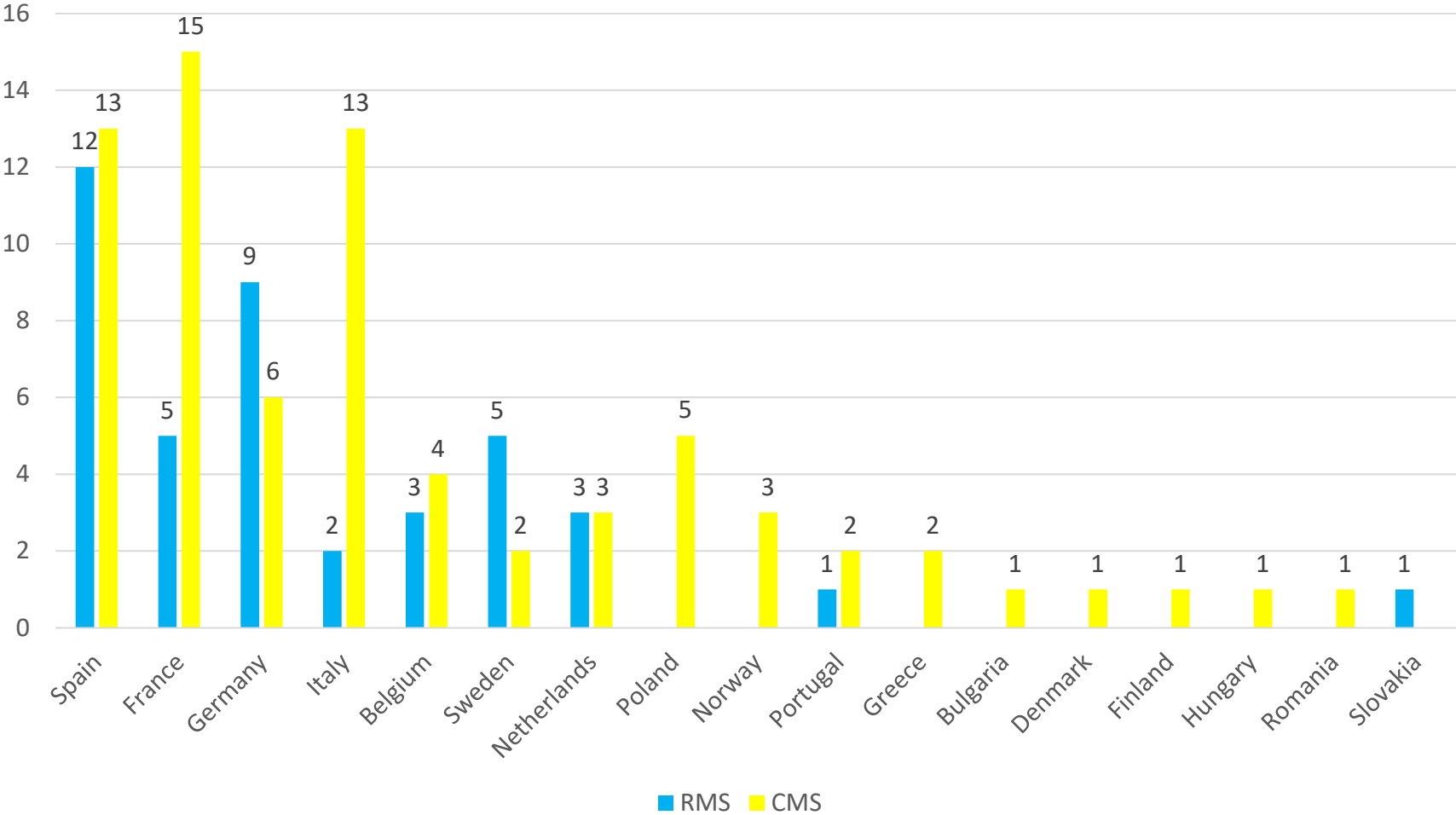
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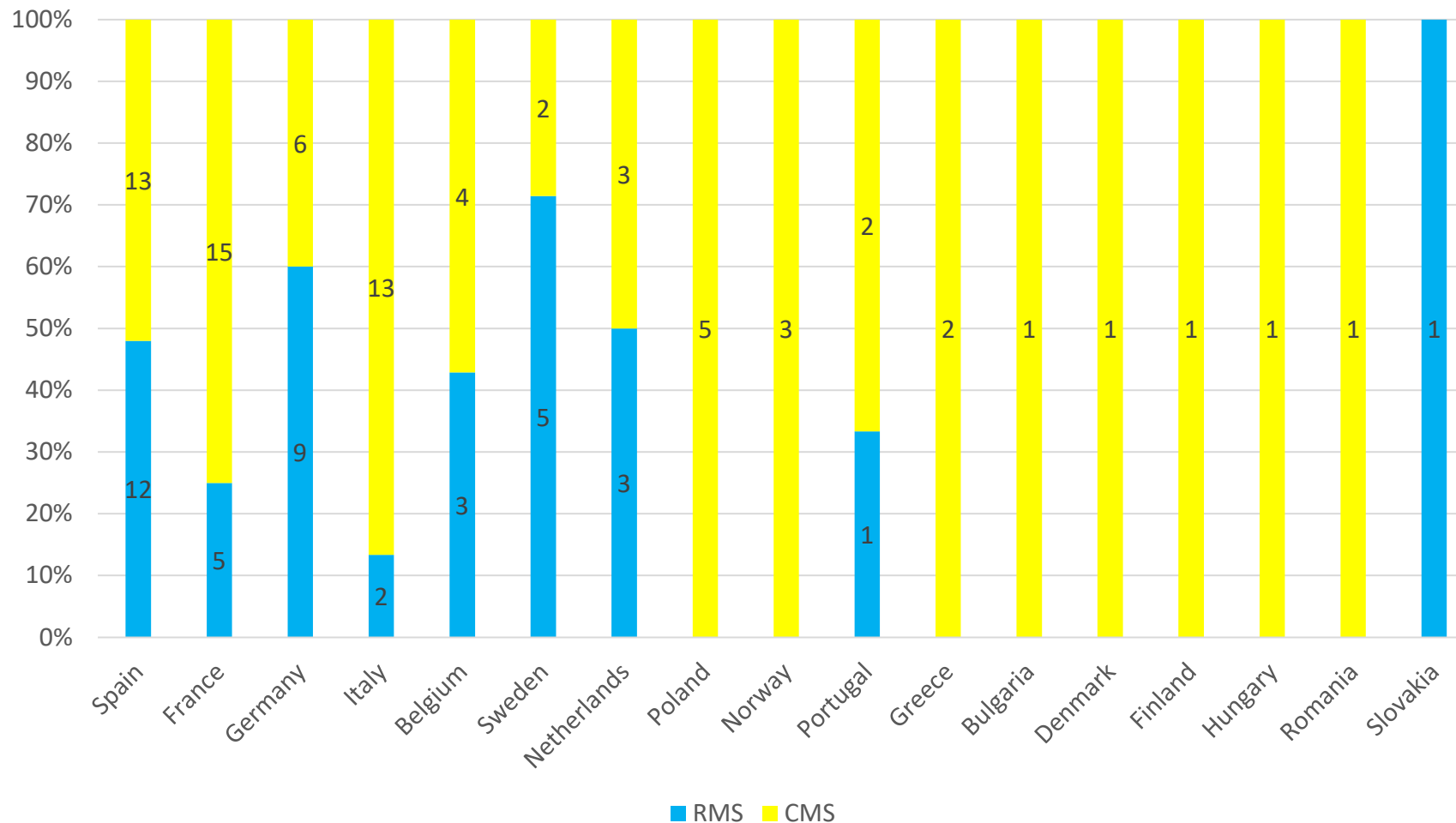
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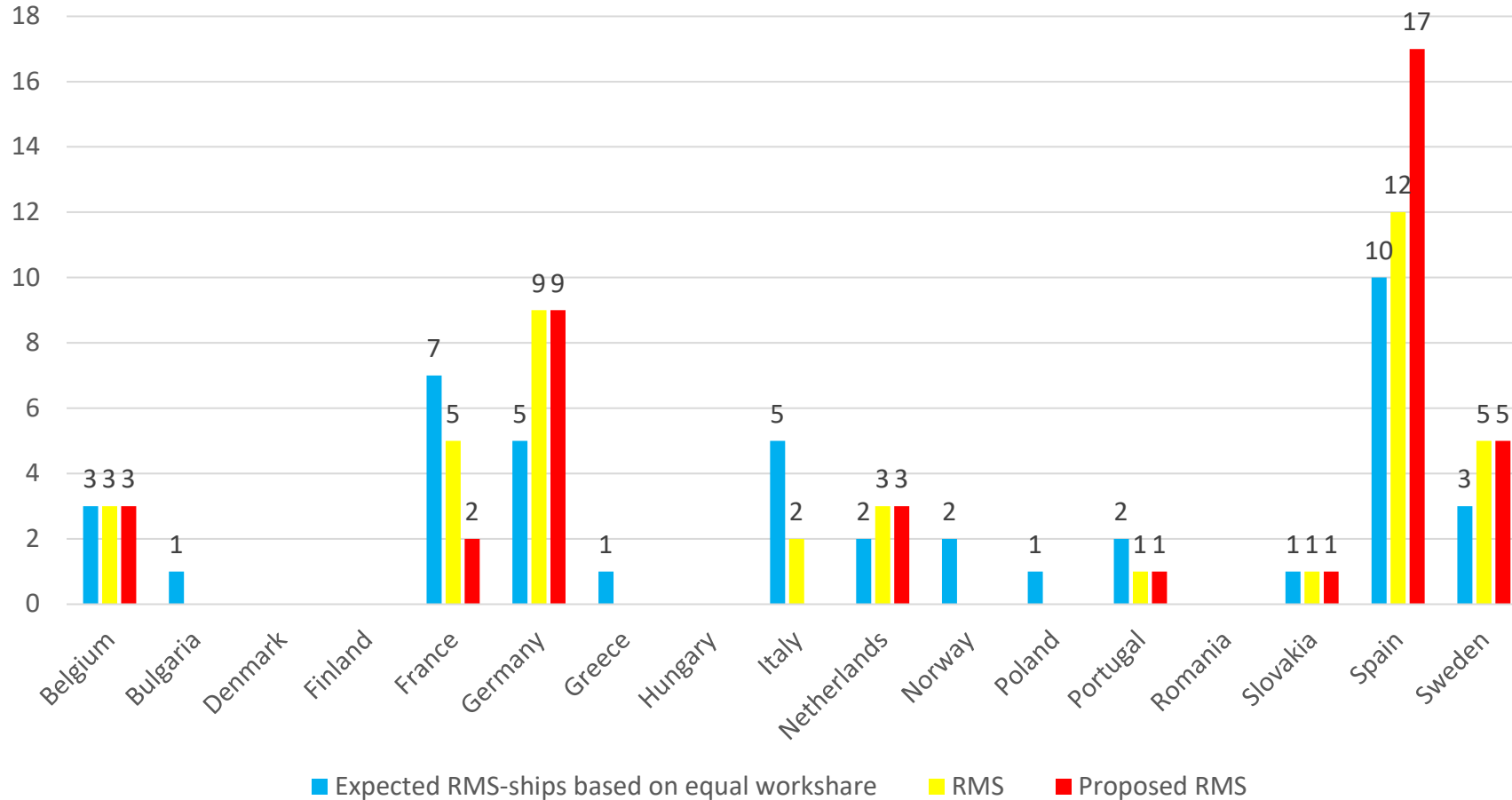


■ RMS ■ CMS



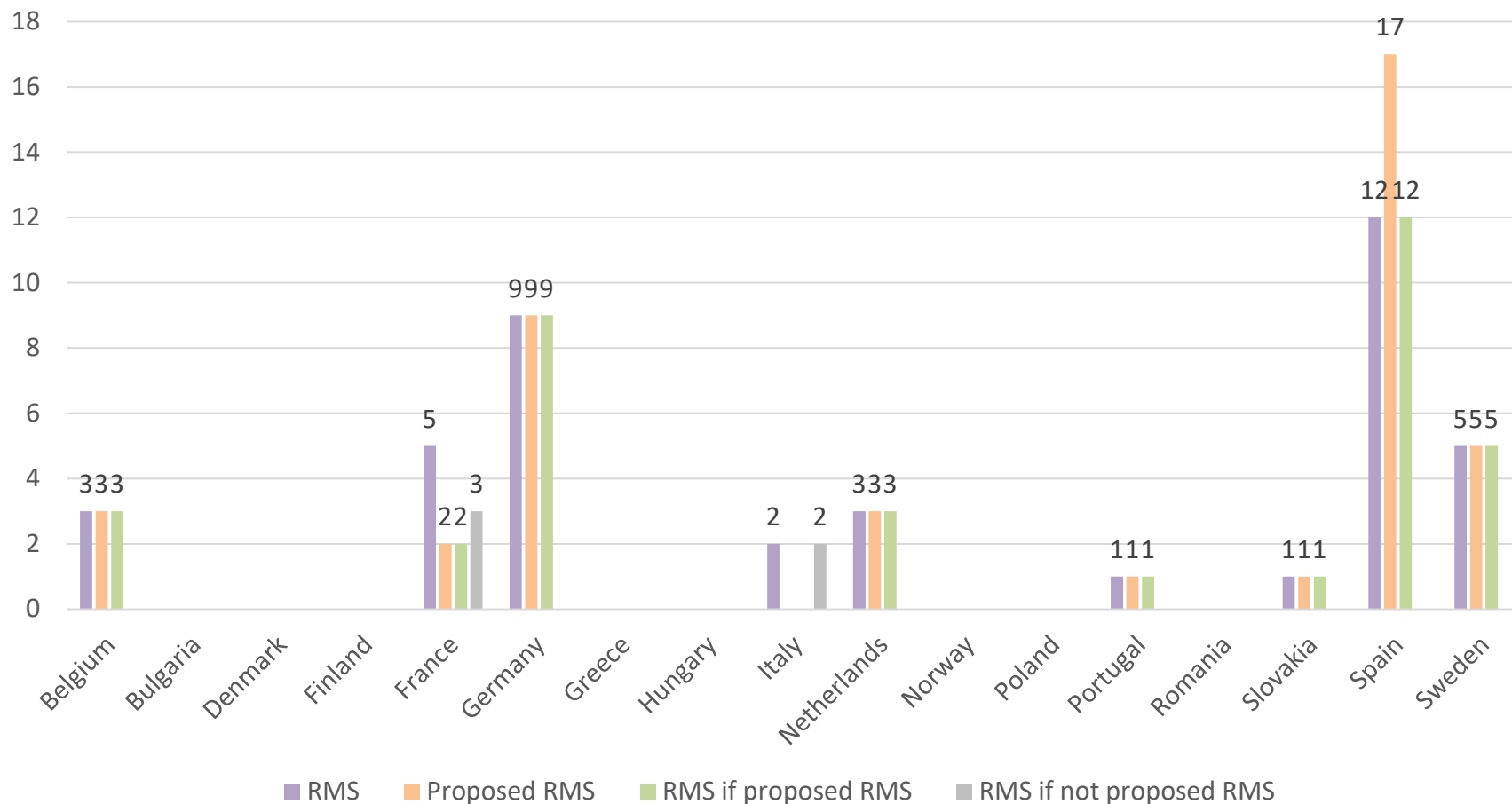
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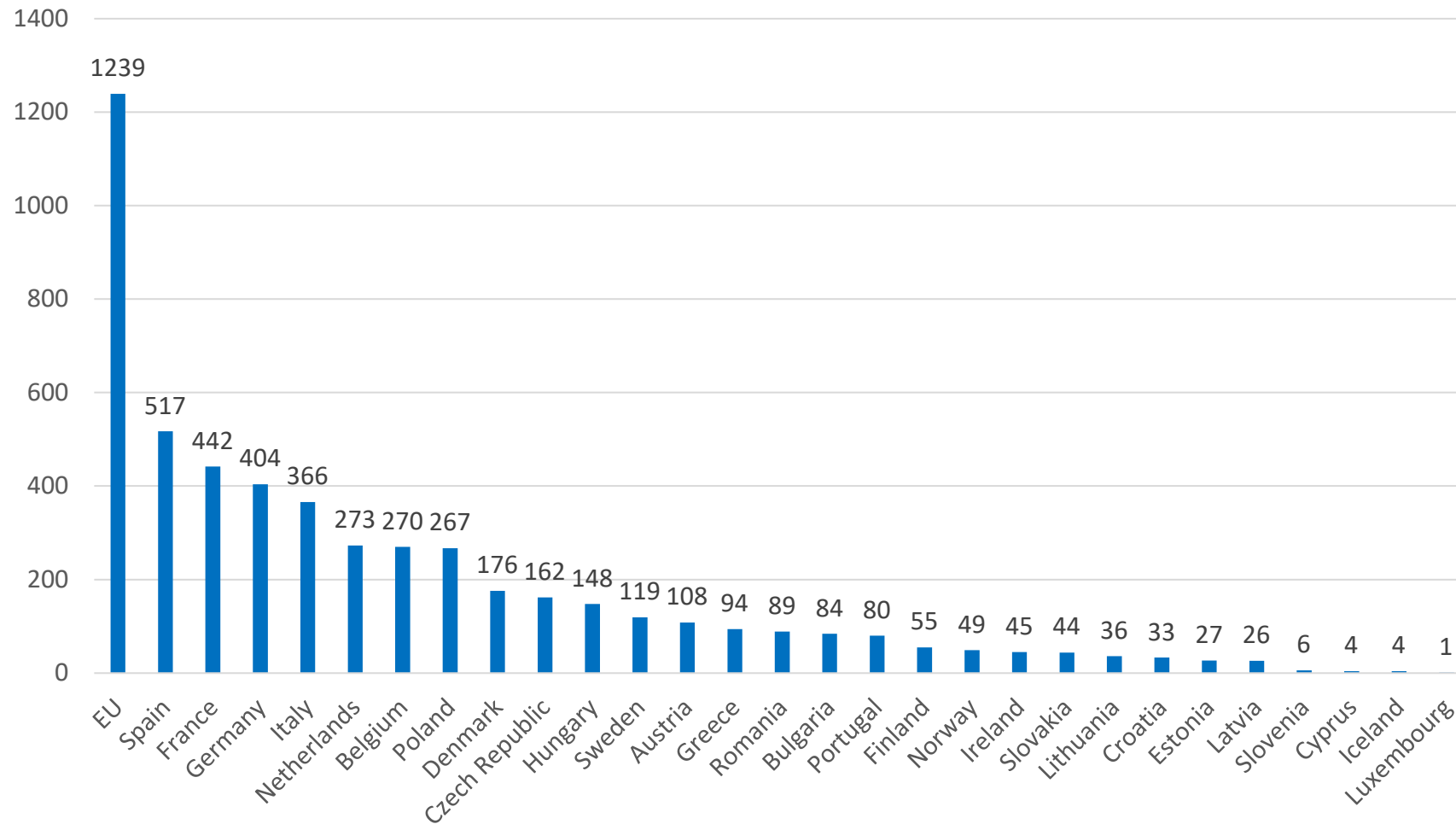
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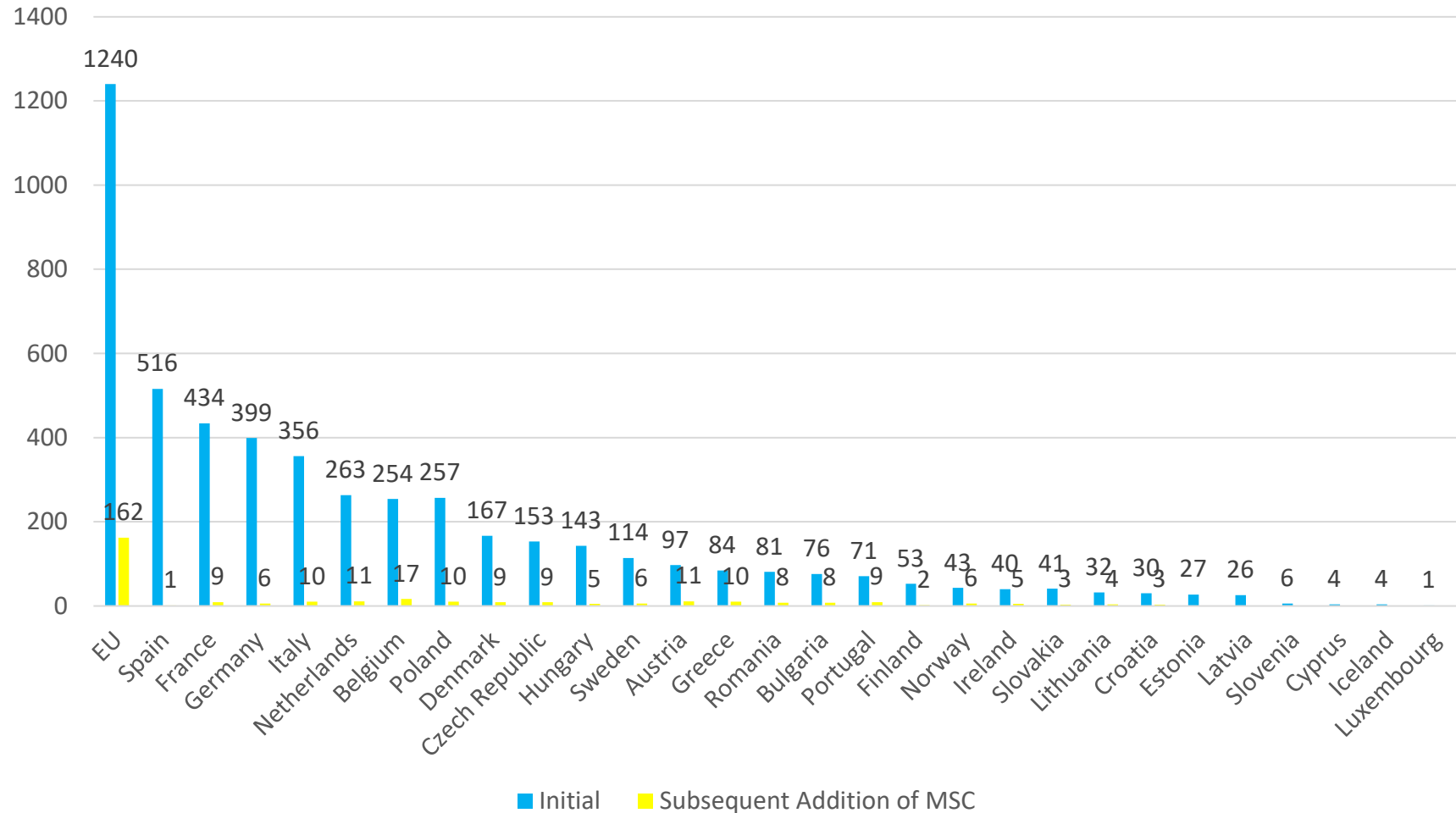
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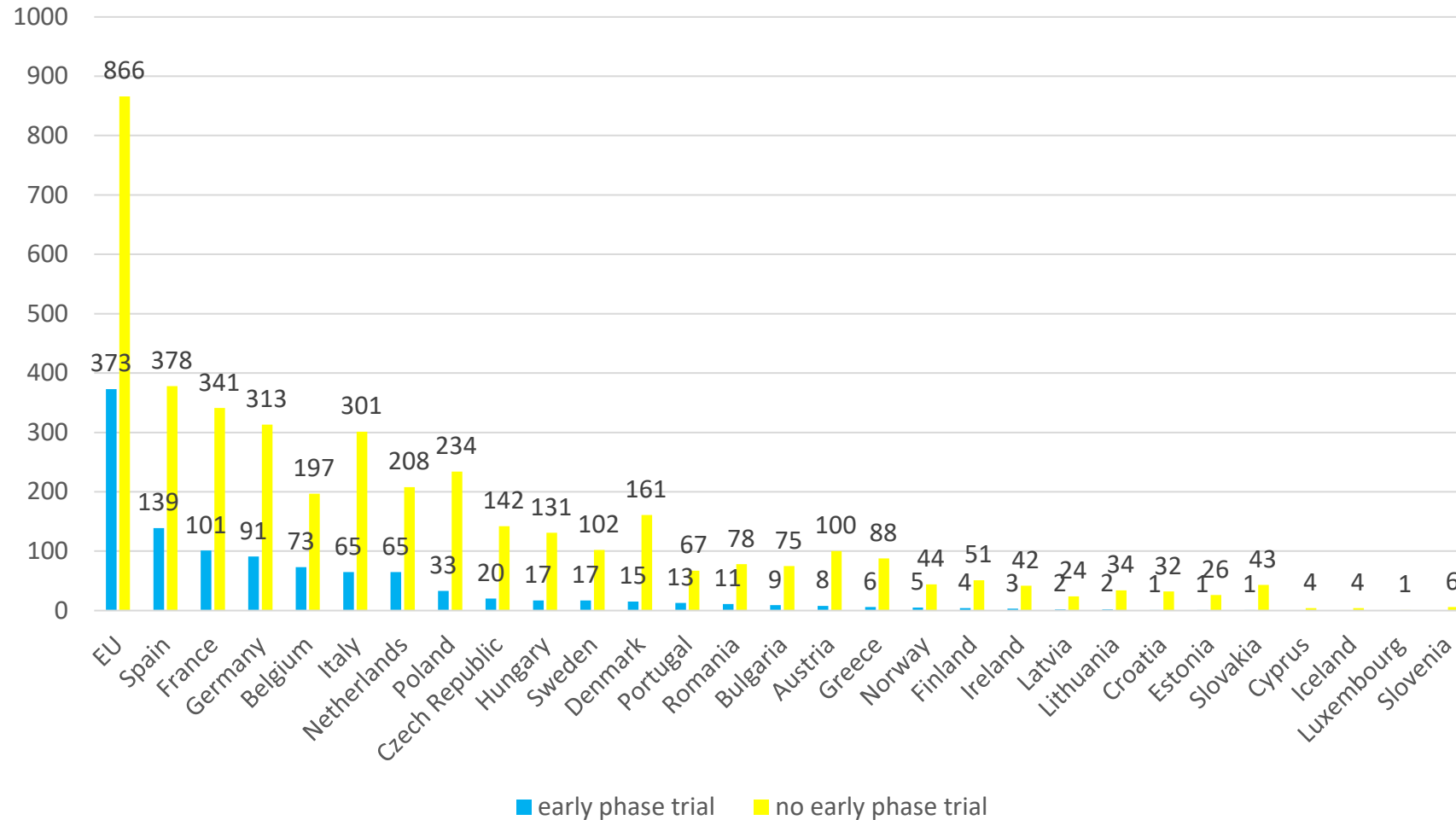
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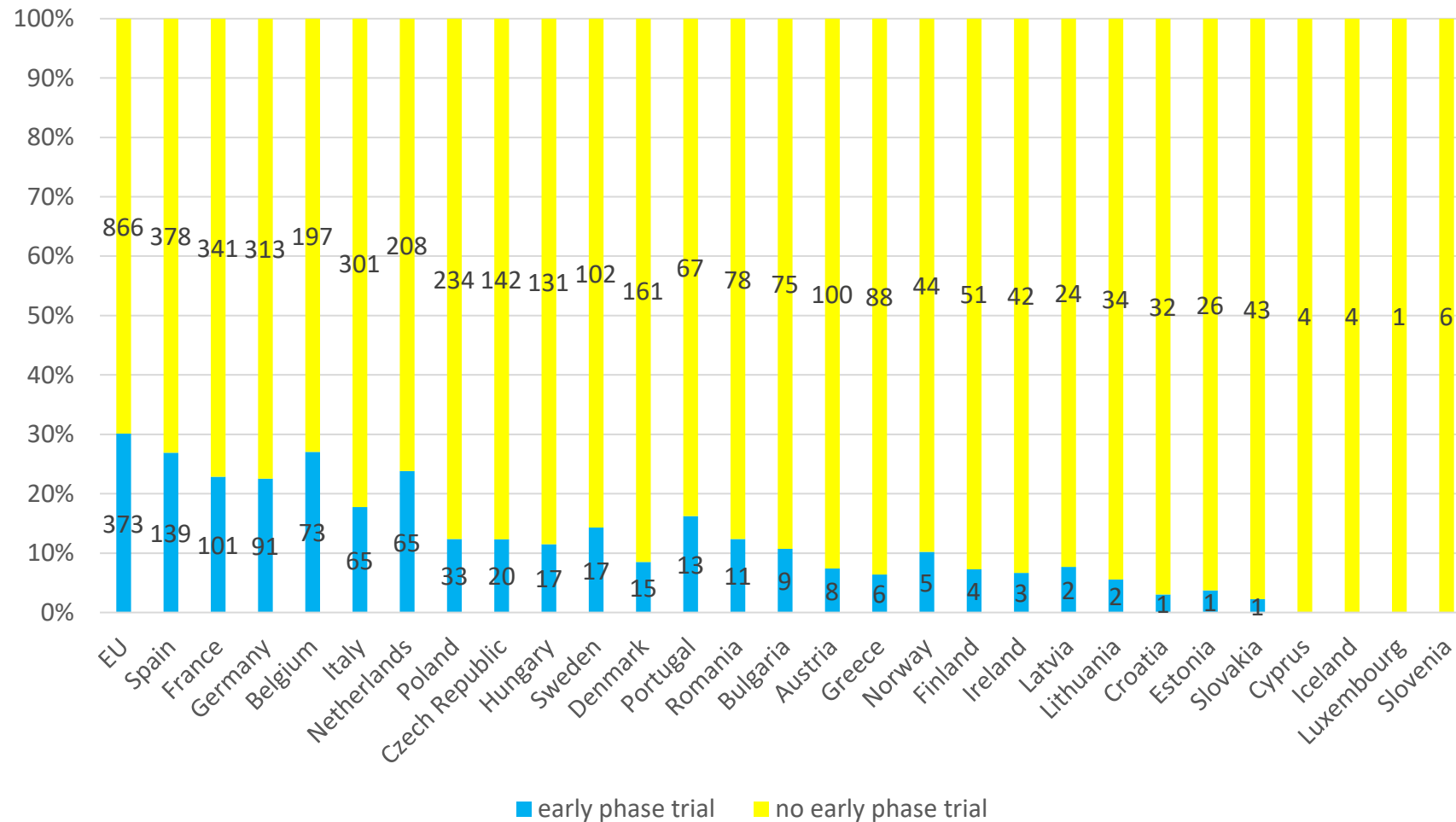
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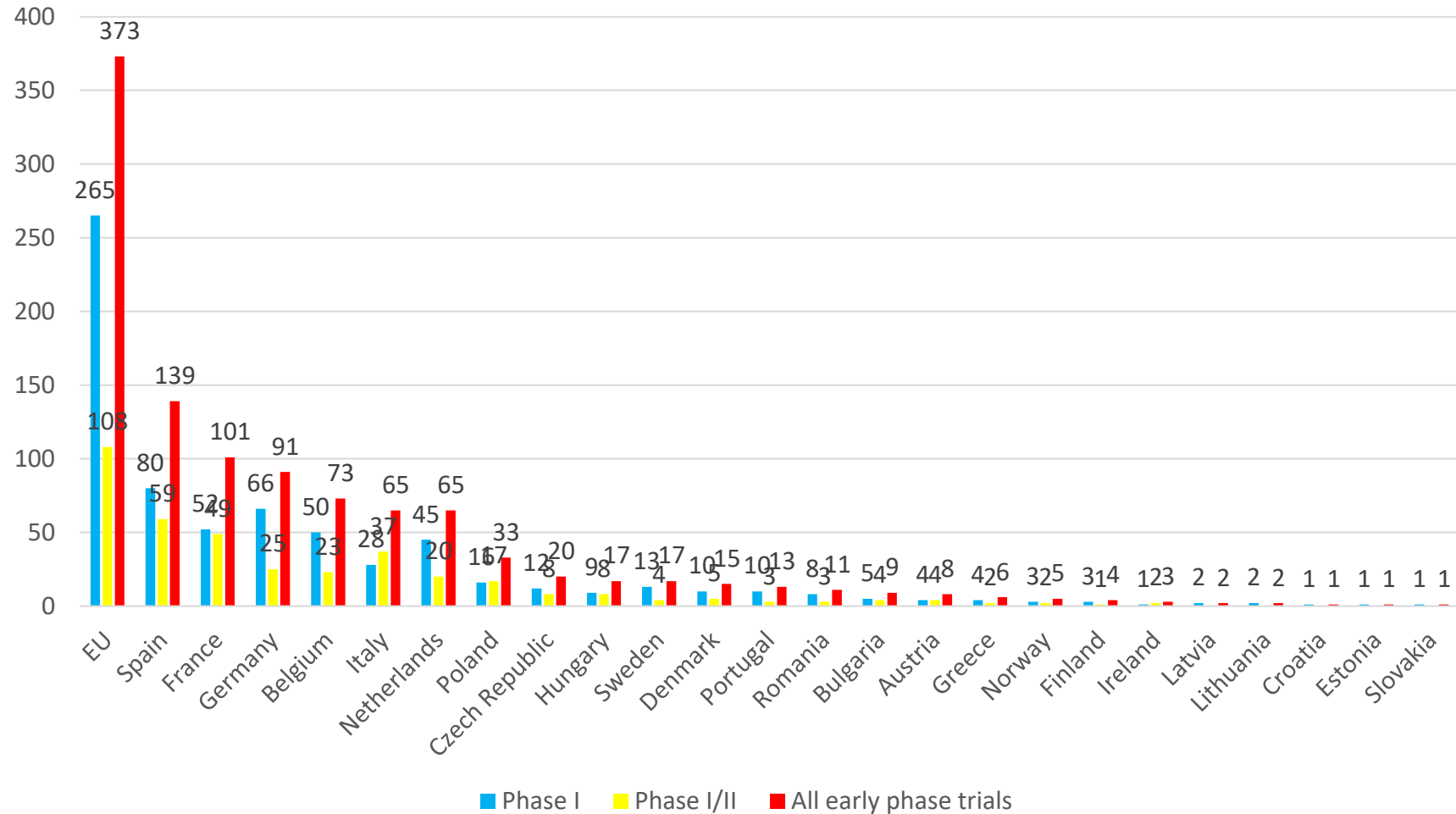
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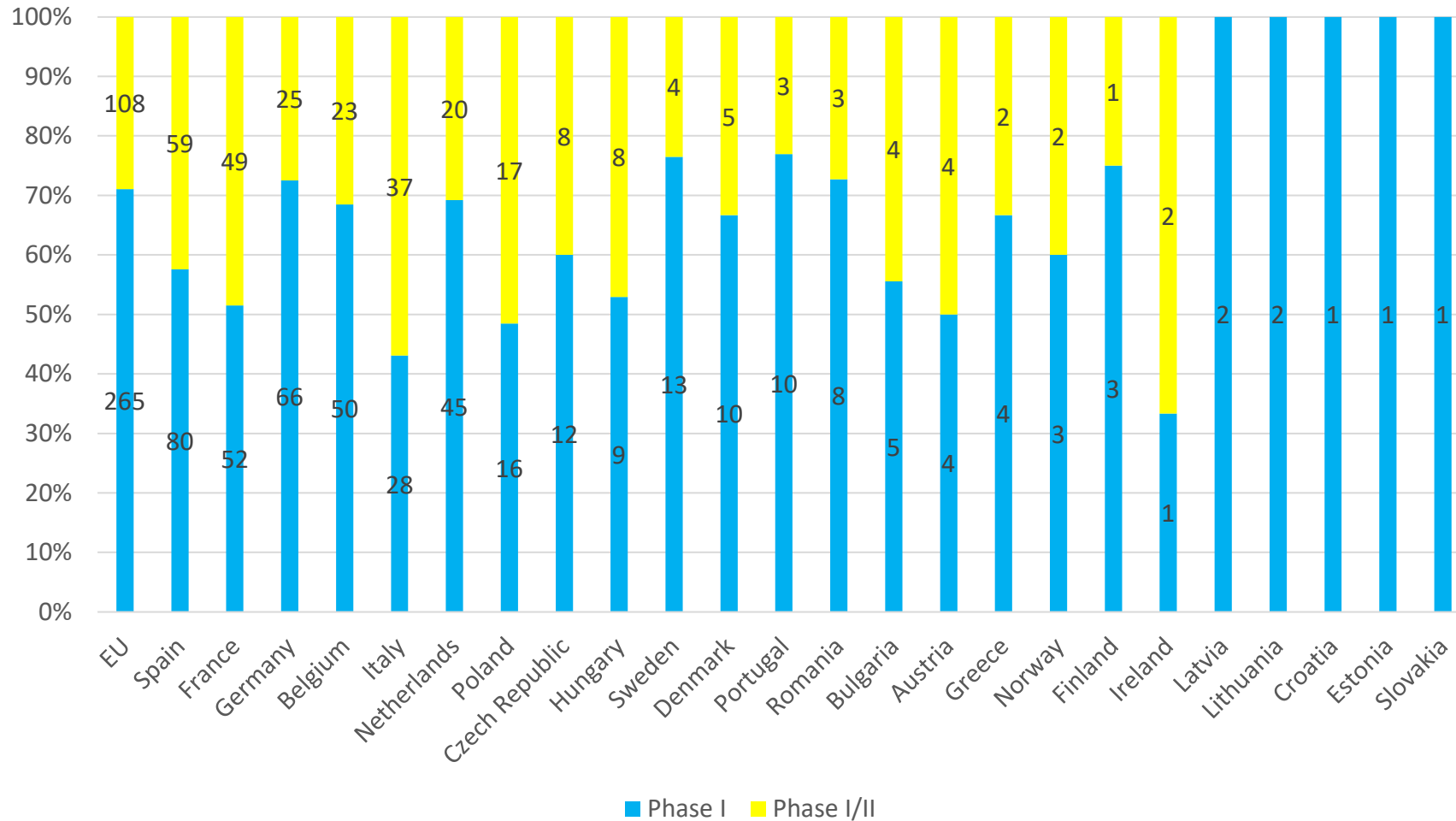
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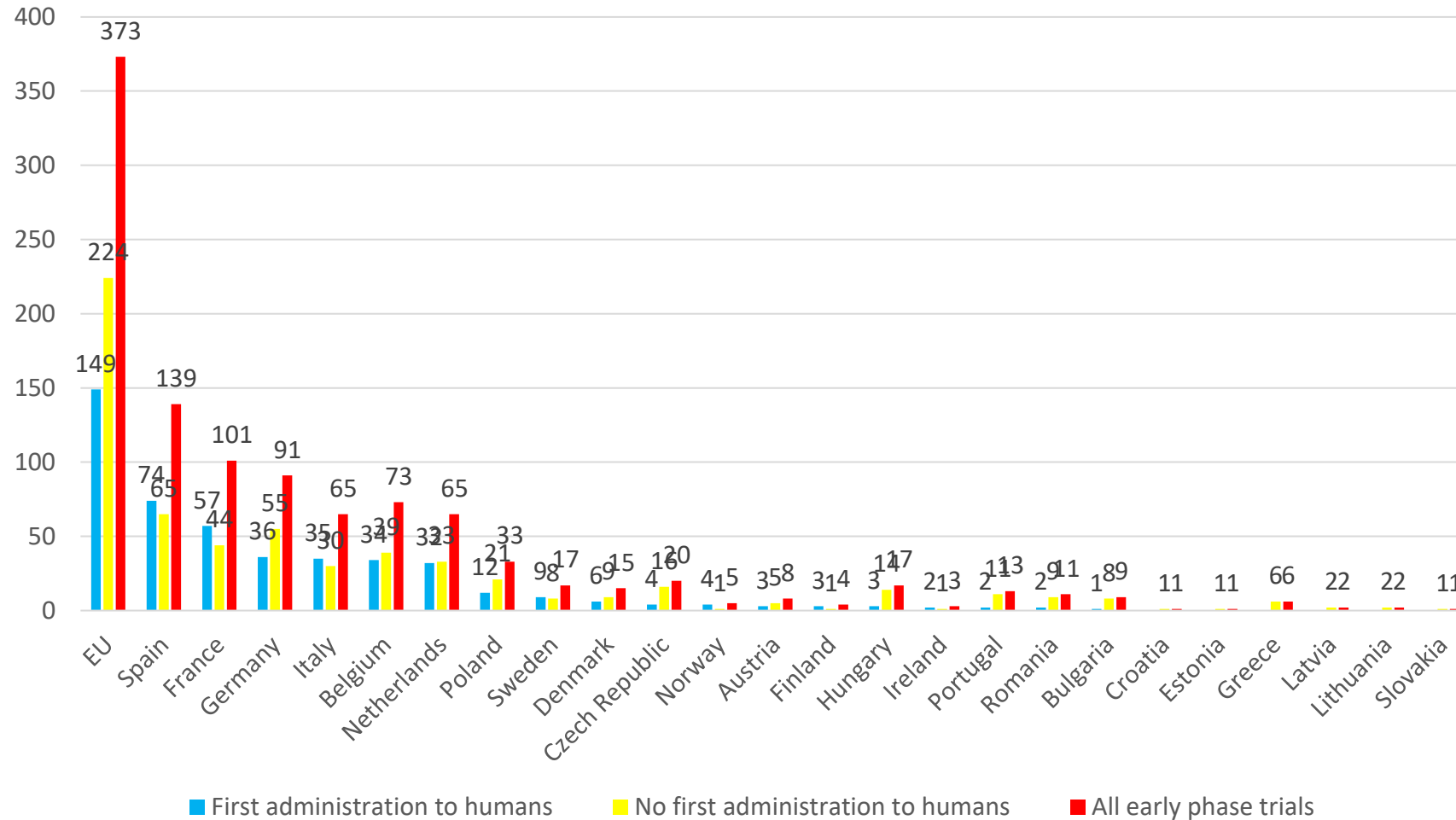
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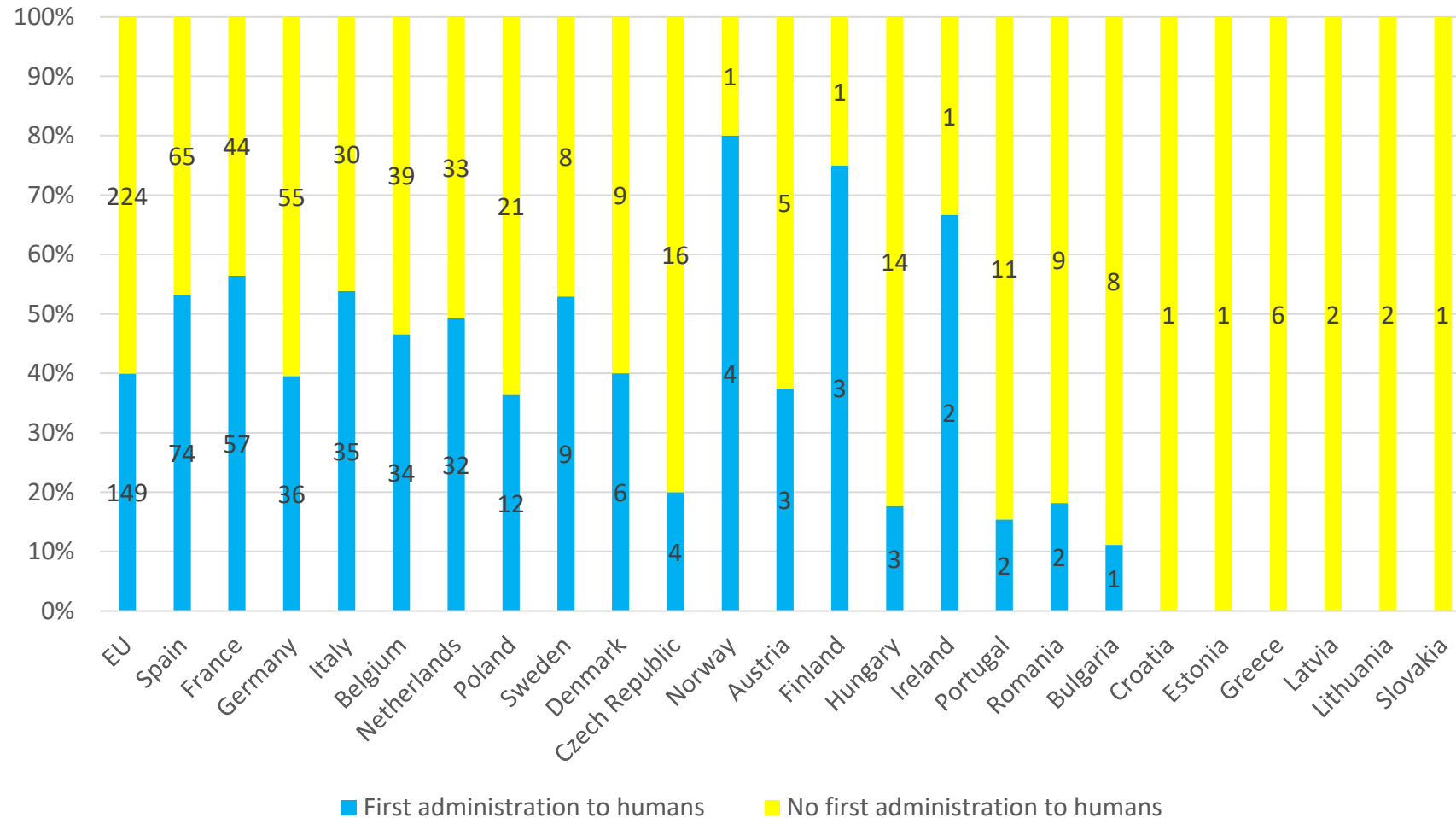
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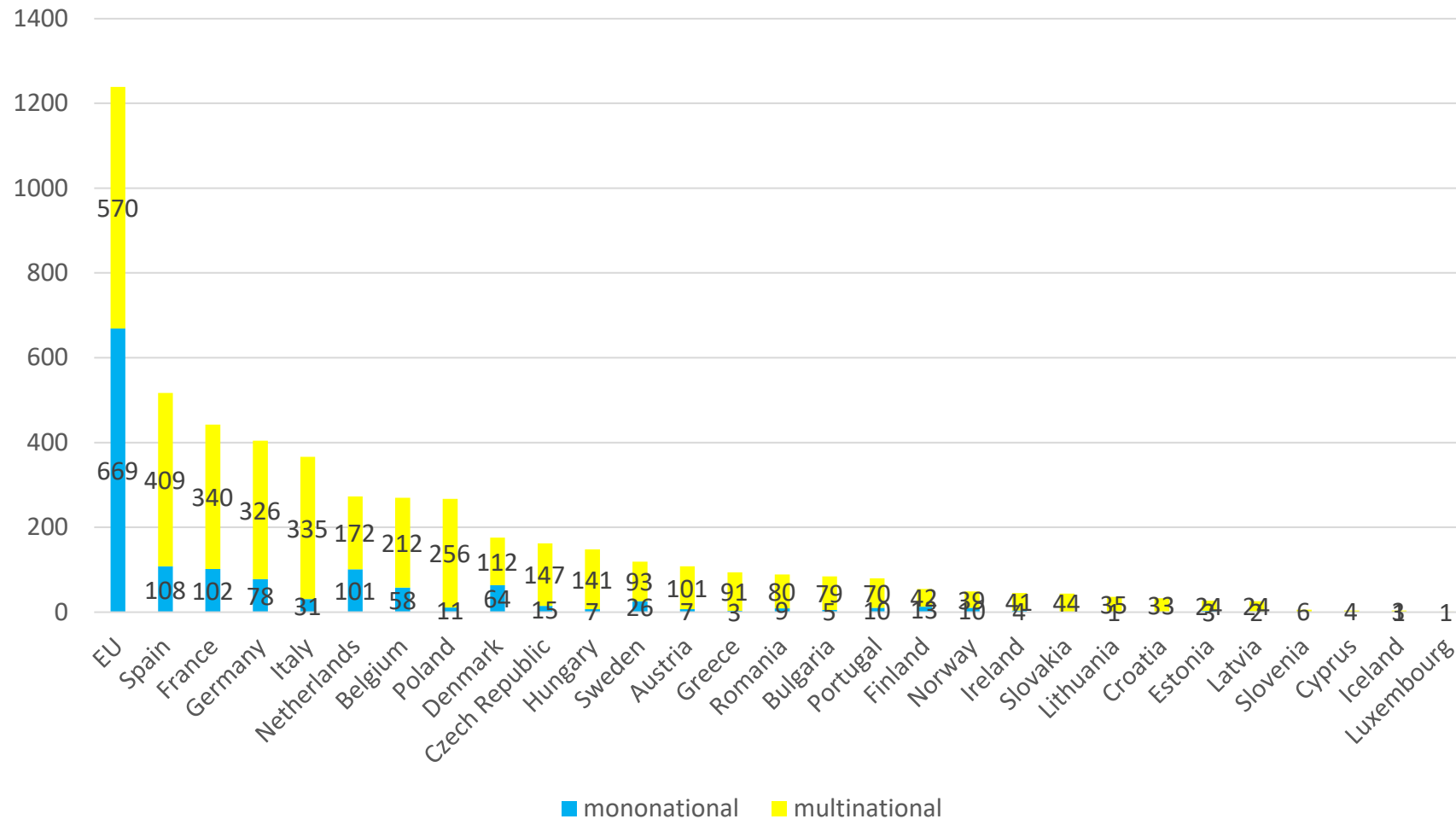
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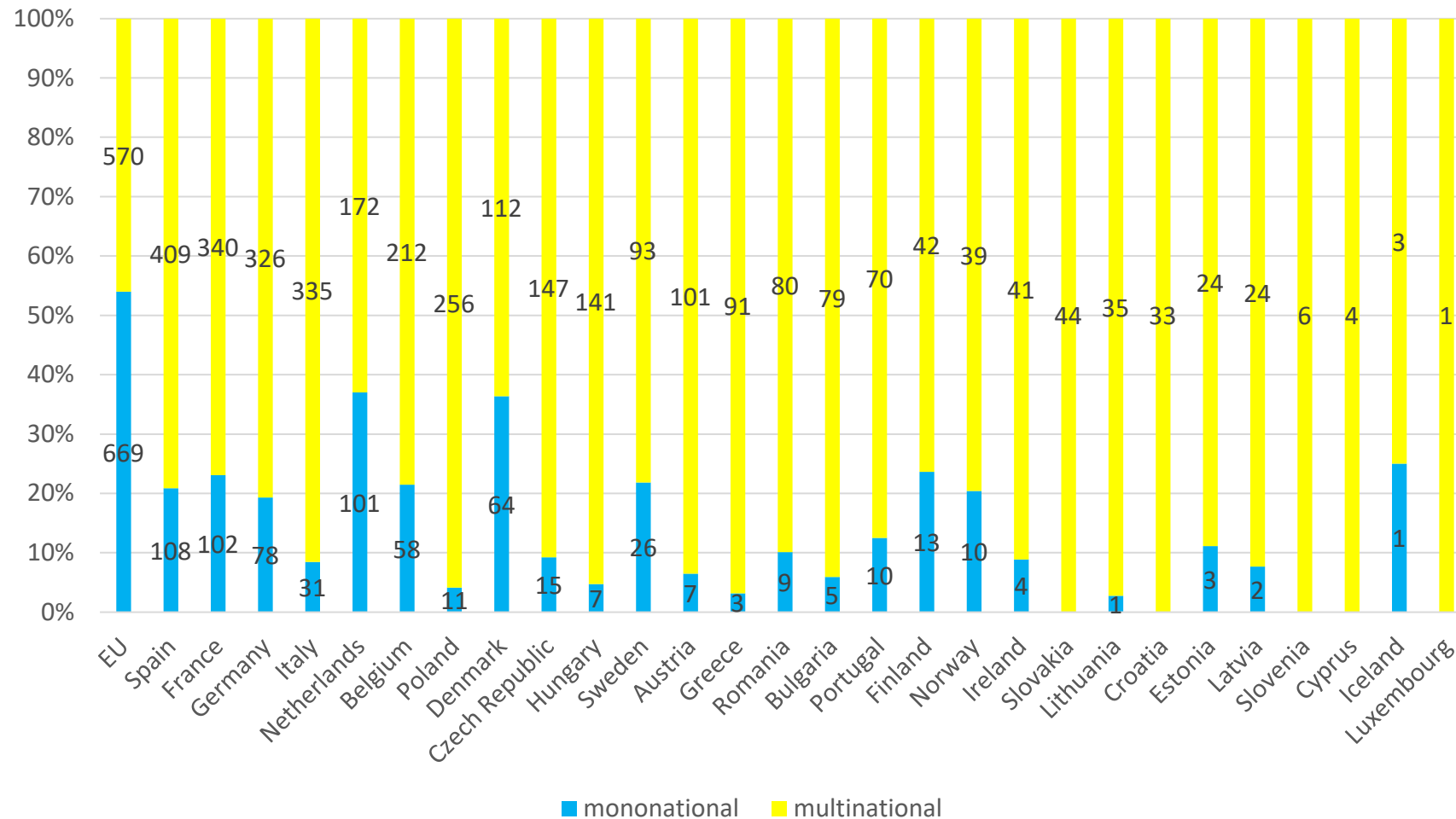
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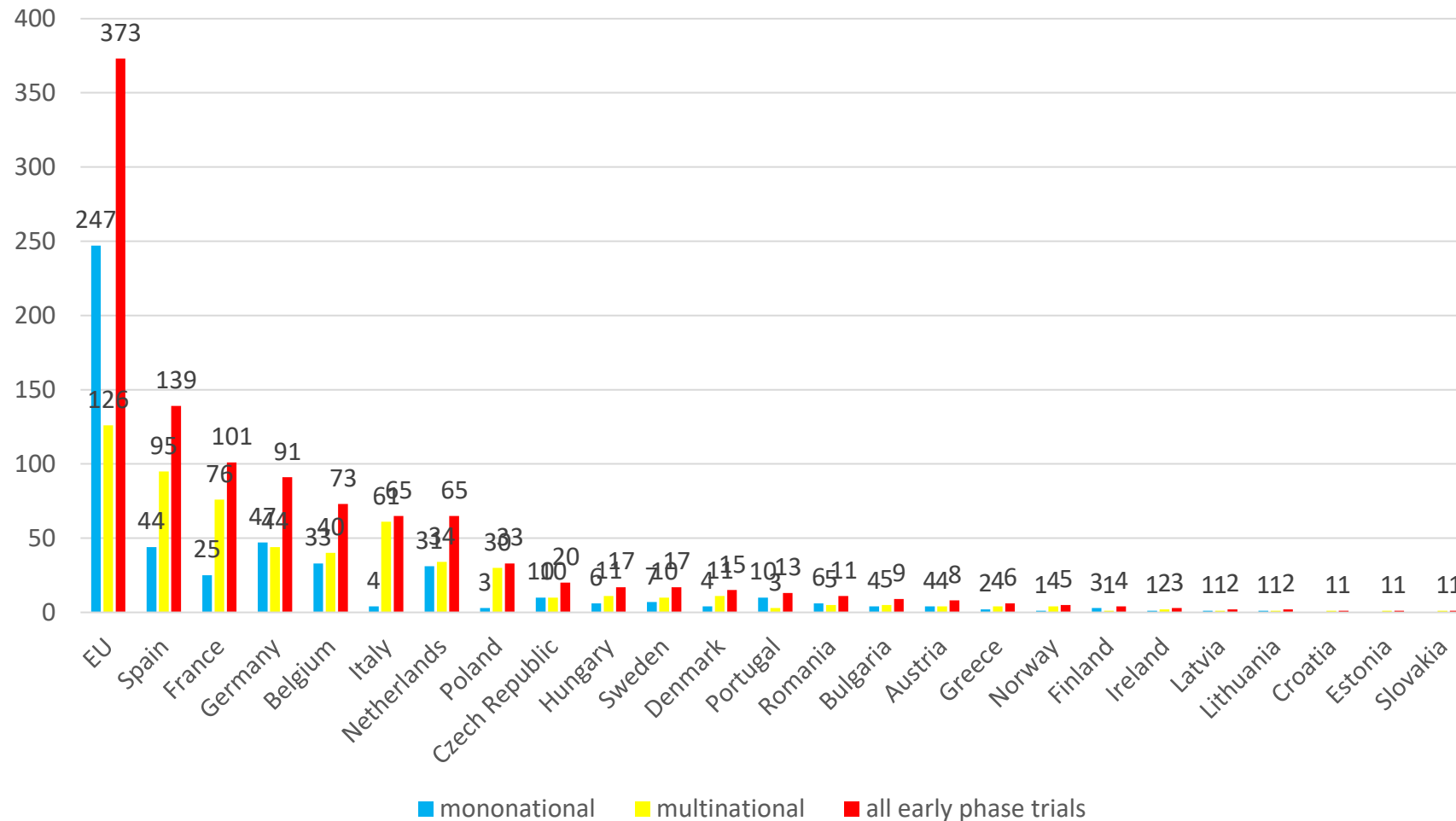
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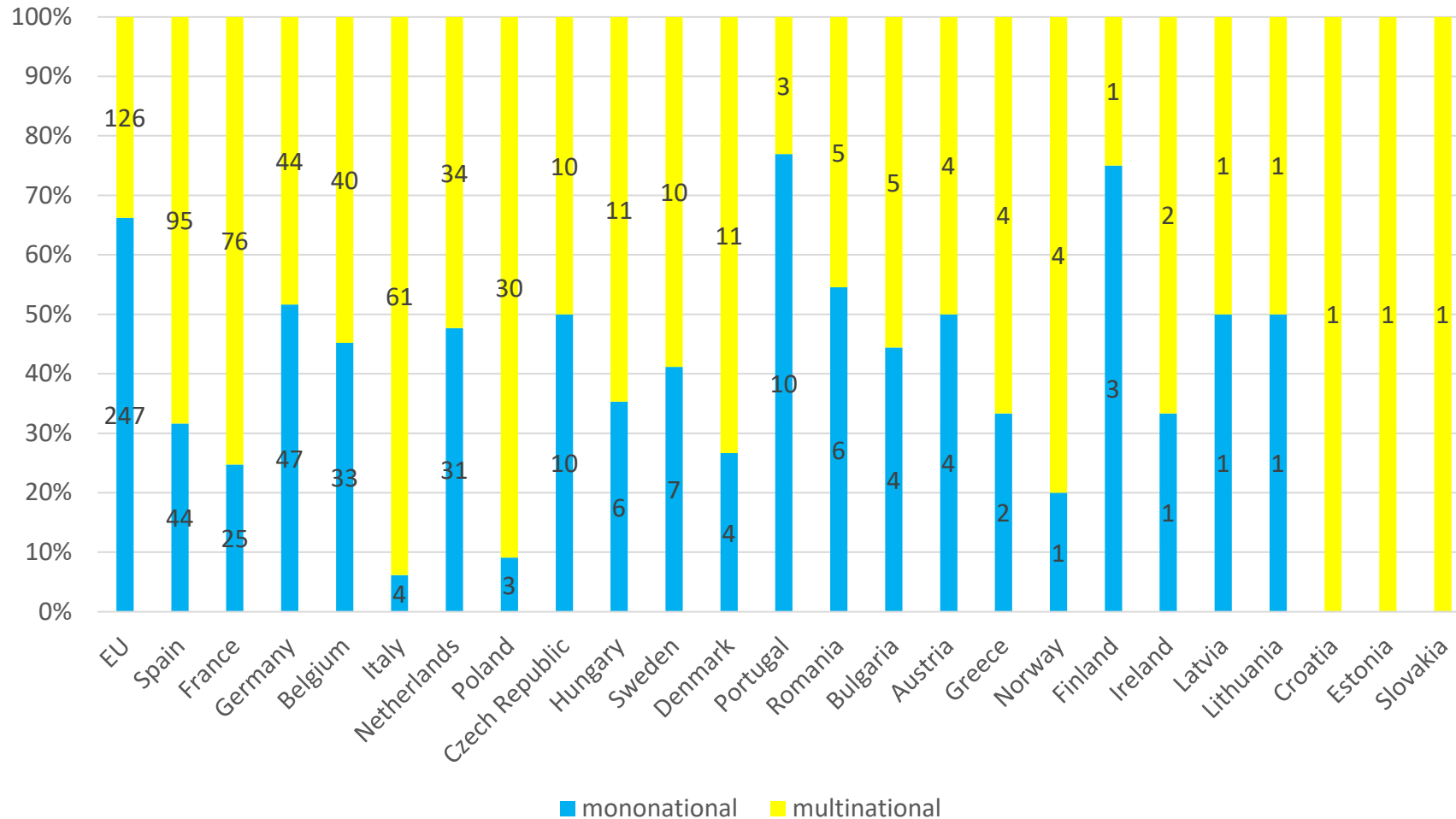
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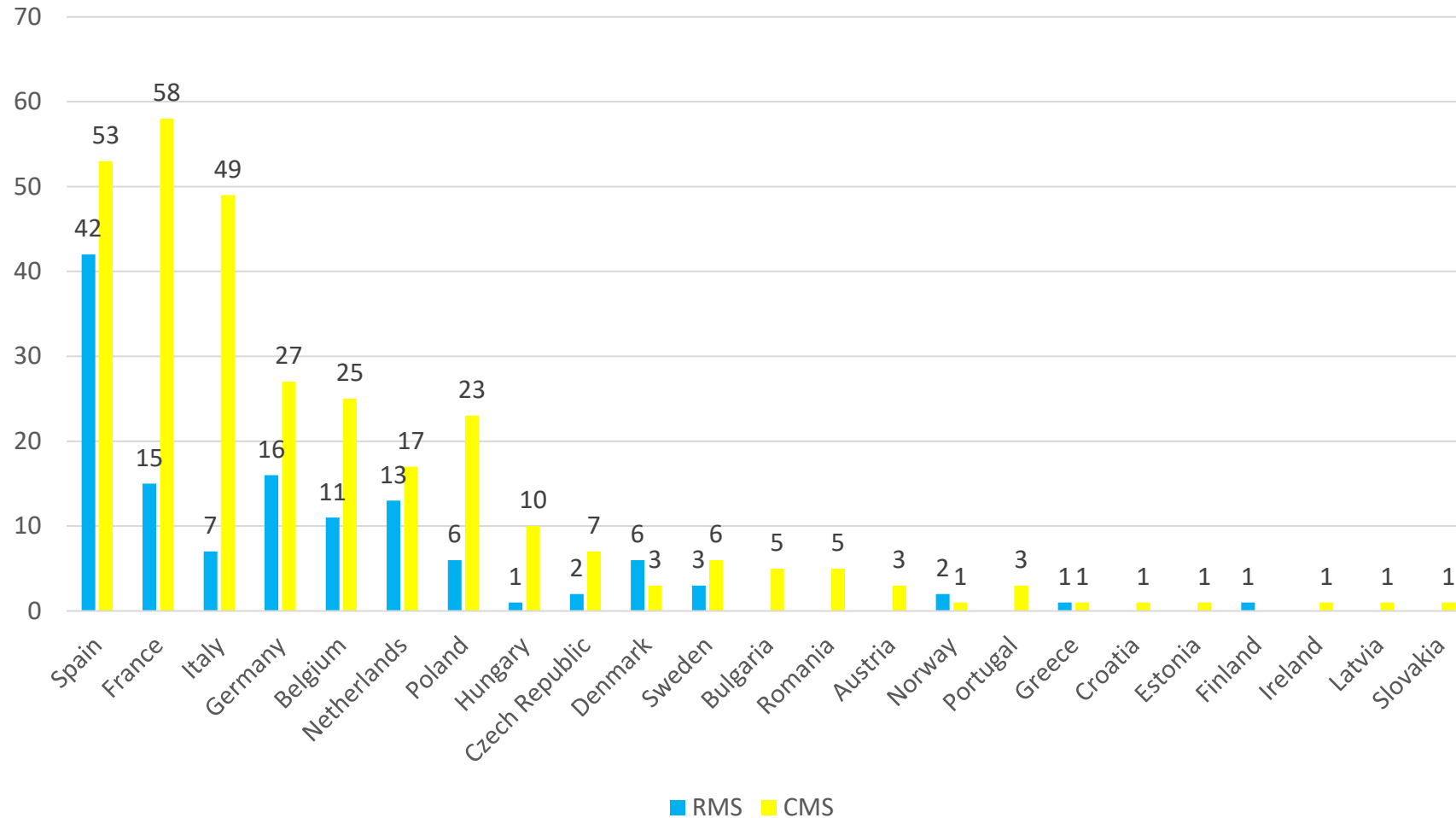
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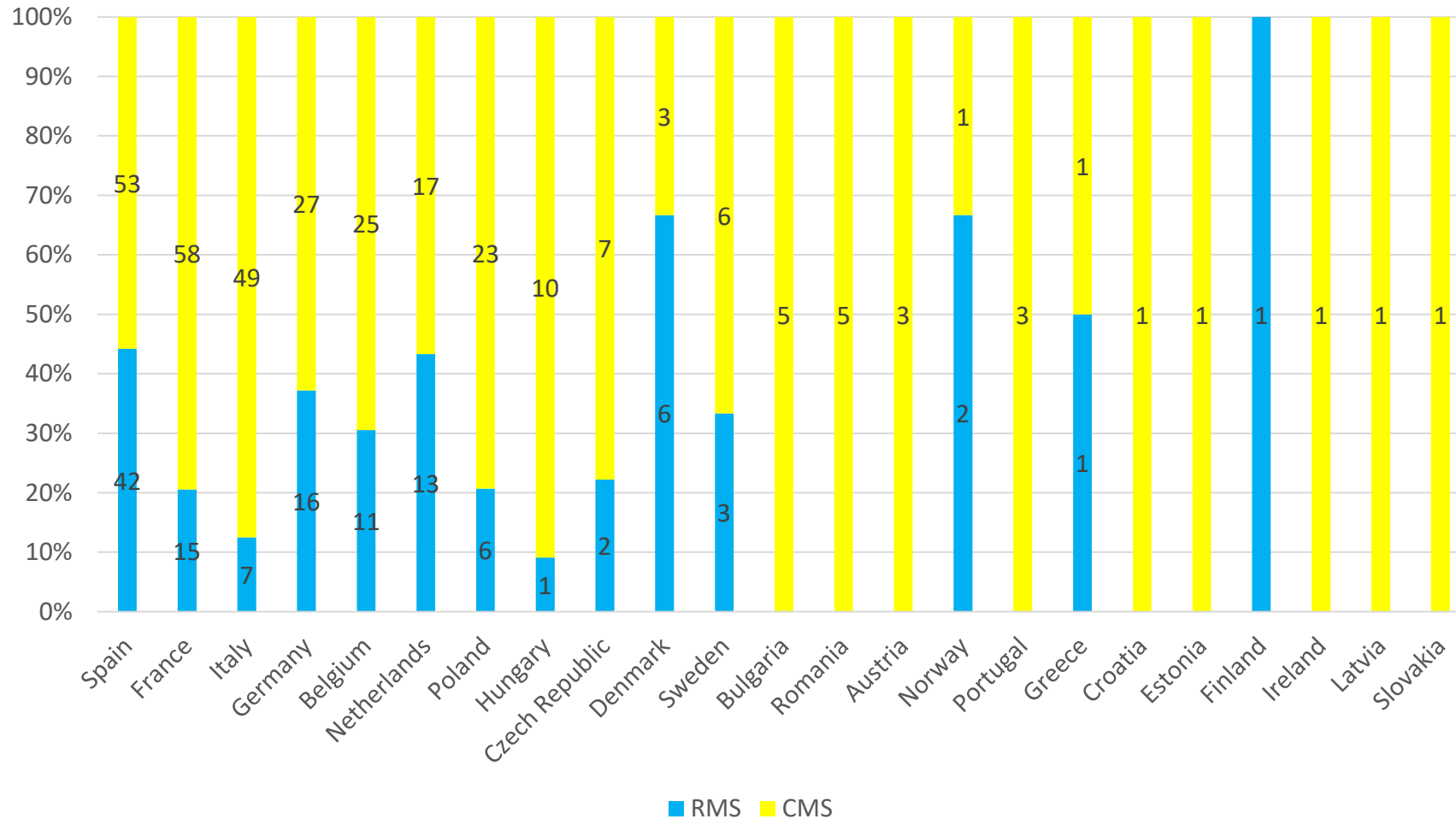
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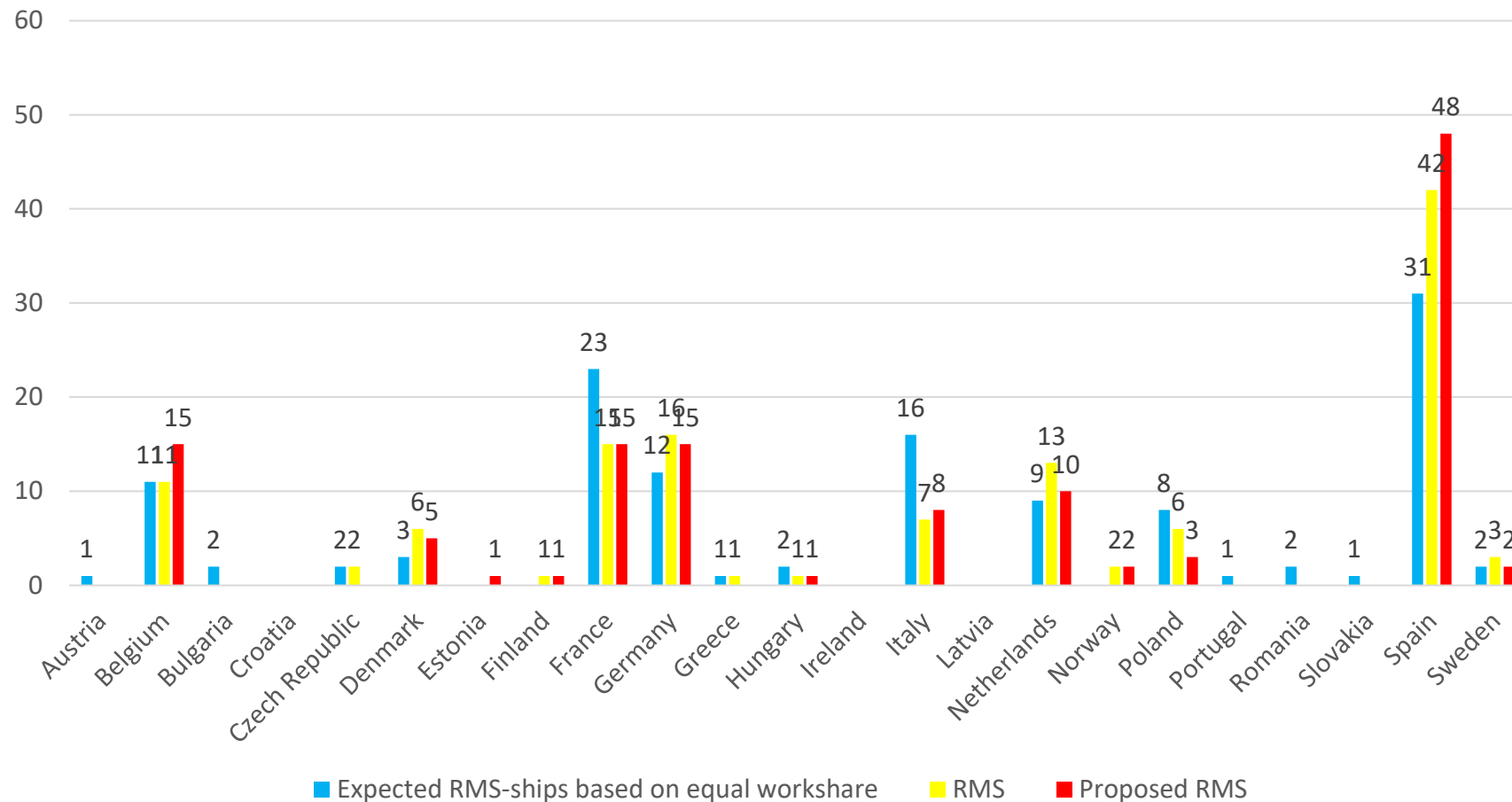
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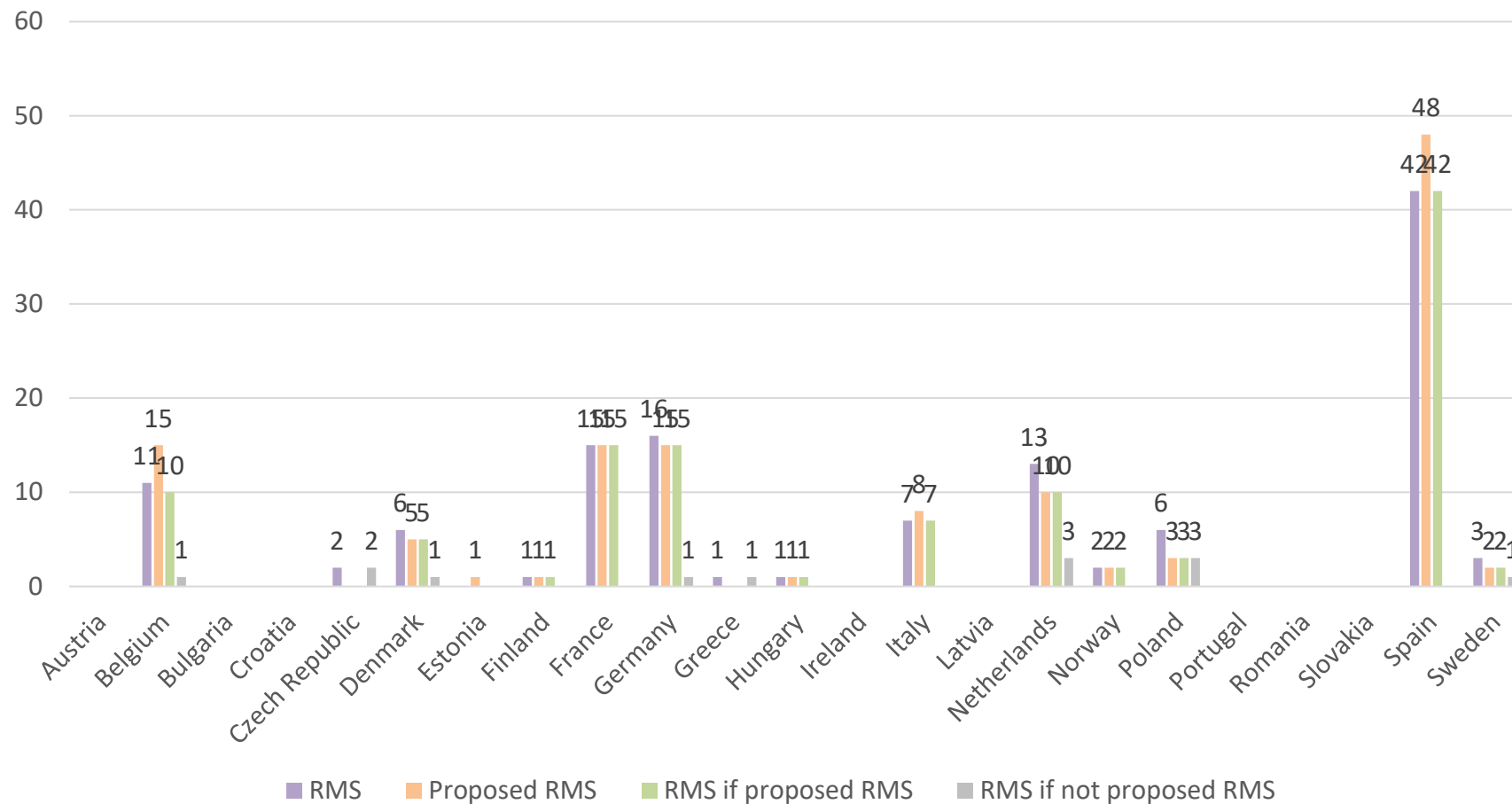
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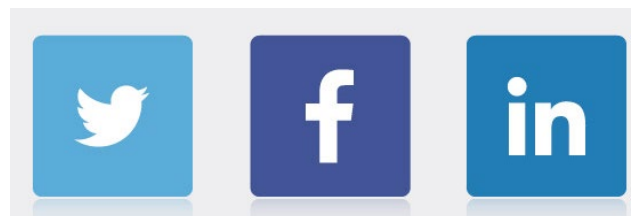
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