Federal Institute
for Drugs
and Medical Devices

Clinical Trials Regulation
- an Update -

Thomas Sudhop, BfArM

Clinical Trials in the EU – A long journey

Before May 2004

National rules only, no harmonisation within the EU

- Paper based submission
- CT authorisation mainly by ethics committees (favourable opinion)
- National competent authorities (NCA) not in all Member States (MS) involved

Directive 2001/20/EC

(since May 2004)

First harmonisation step, but still many national specificities

- Electronic application form but otherwise paper based submission
- Both, NCA + ethics committee (EC) involved, but work independently of each other and issue own decisions

Regulation (EU) No 536/2014 (CTR)

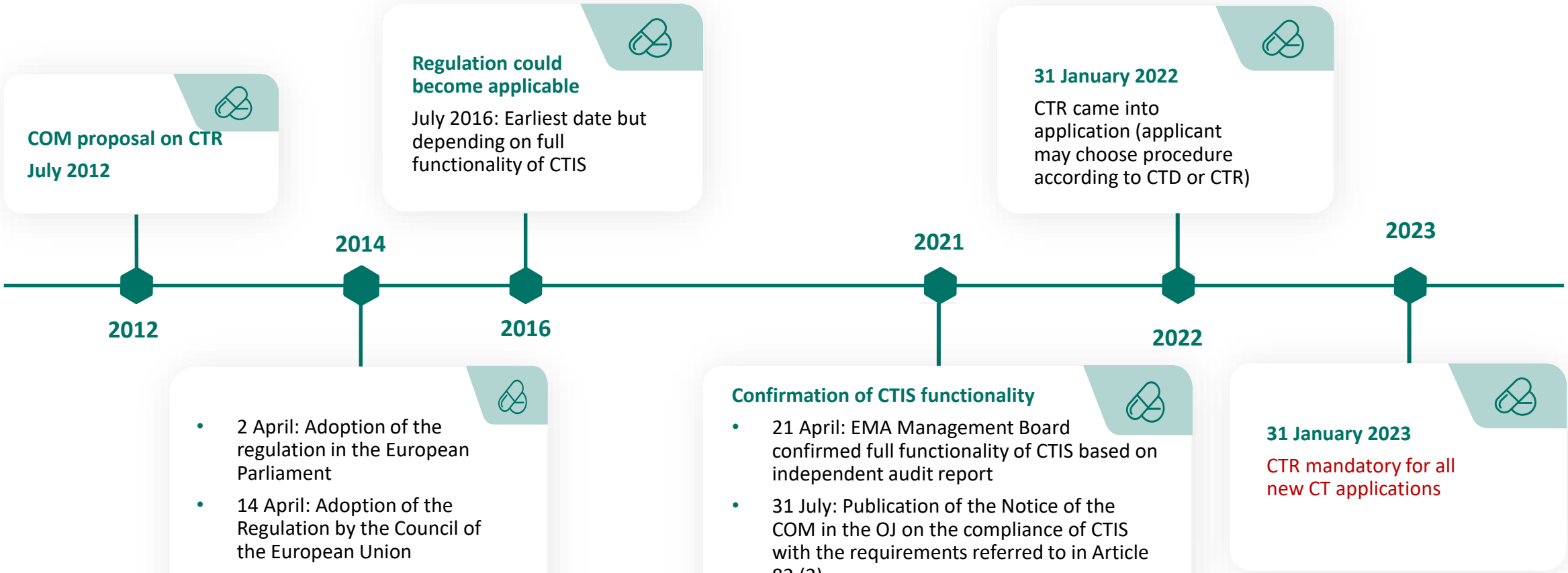
(May 2014 + January 2022/23)

Full harmonisation and joint assessment of multi-state trials

- E-submission through EU portal (CTIS) for all MS
- Joint assessment of all Member States concerned (MSC)

The CTR

10 years path from proposal to coming into application. Now mandatory!



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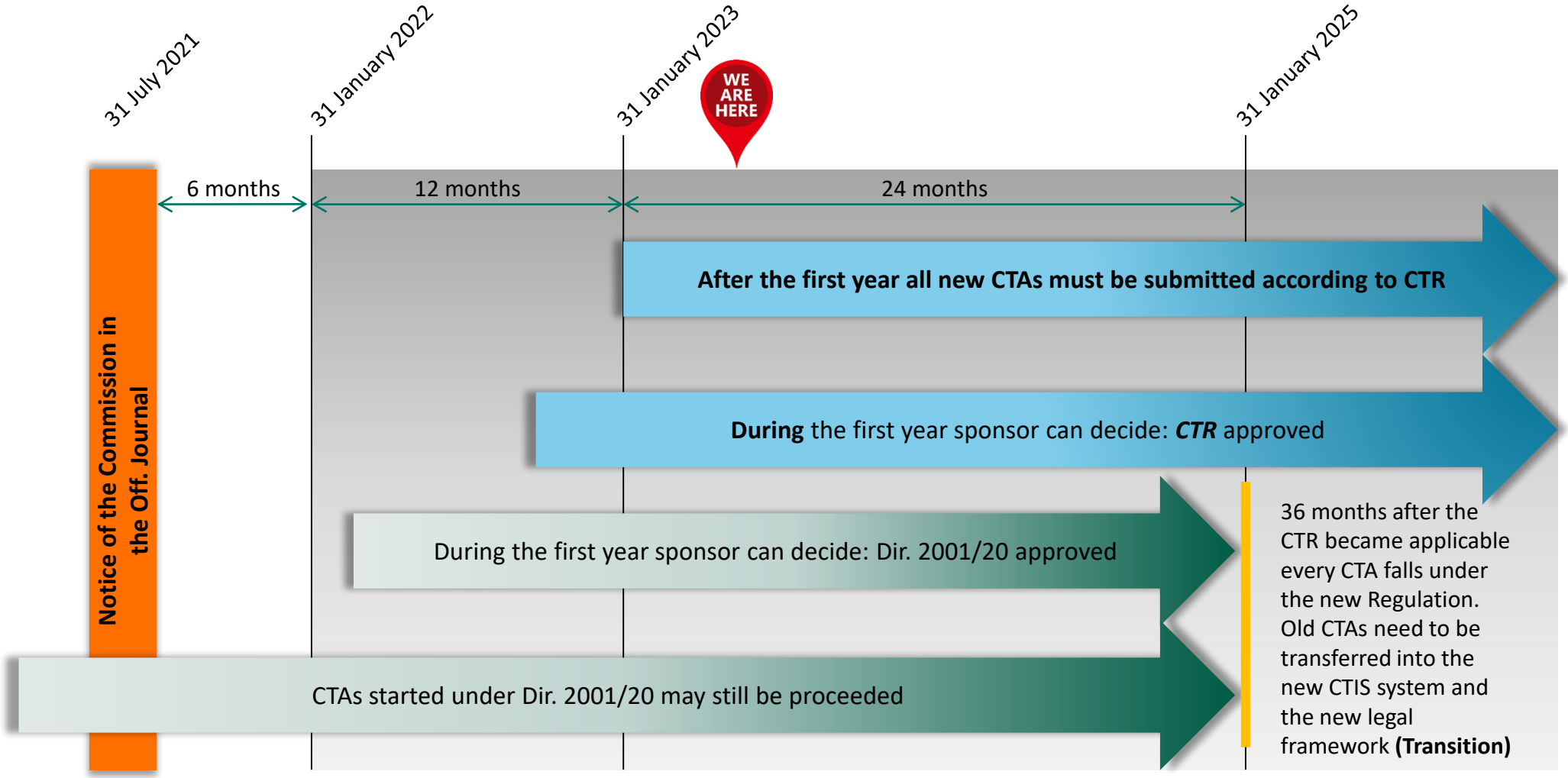
Transition period of the CTR



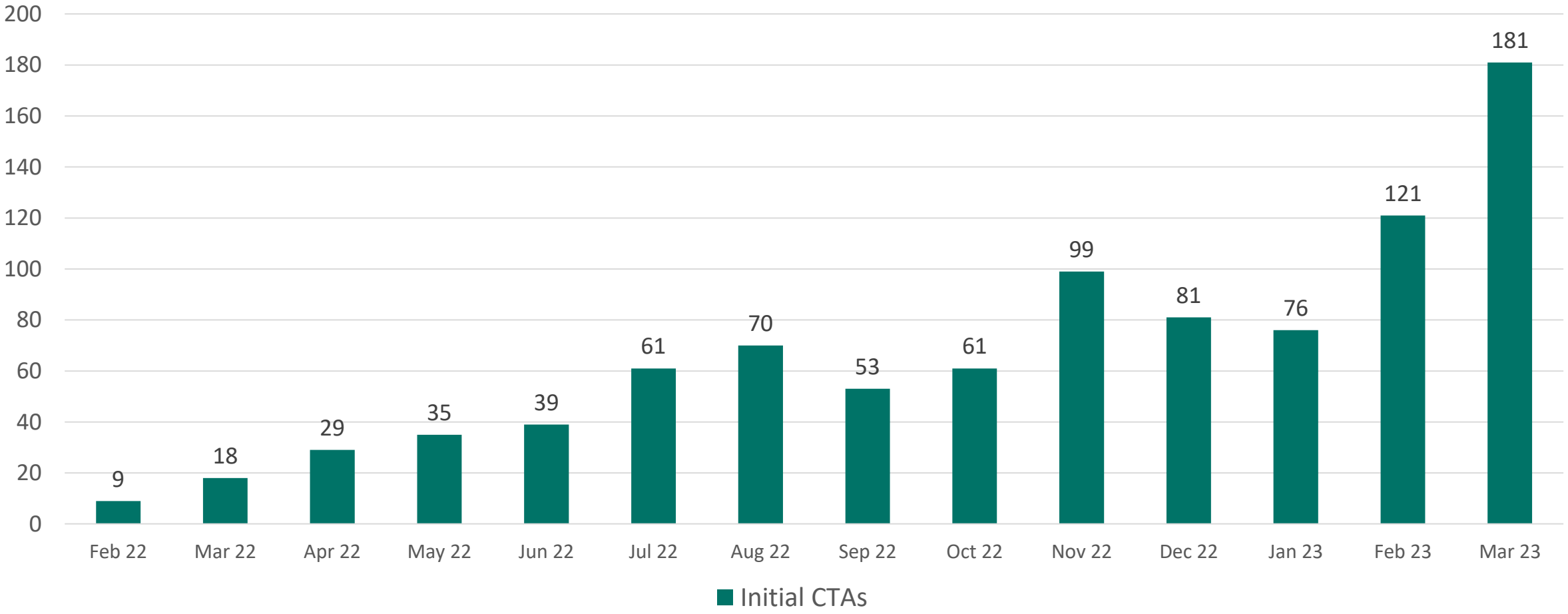
Current Status

- CTR became applicable on 31 January 2022 (facultative)
- CTR became *mandatory* on 31 January 2023 for new CTAs
- Authorised CTAs running under the Clinical Trials Directive (CTD) can be continued under the CTD framework until 31 January 2025
- After 31 January 2025 all active clinical trials hat to be transferred into the CTR framework and all required documents had to be uploaded to CTIS (Transition)

CTIS Statistics (31 Jan 2022 – 28 Feb 2023)

CTIS statistics: Initial CTA submissions

31 January 2022 – 31 March 2023



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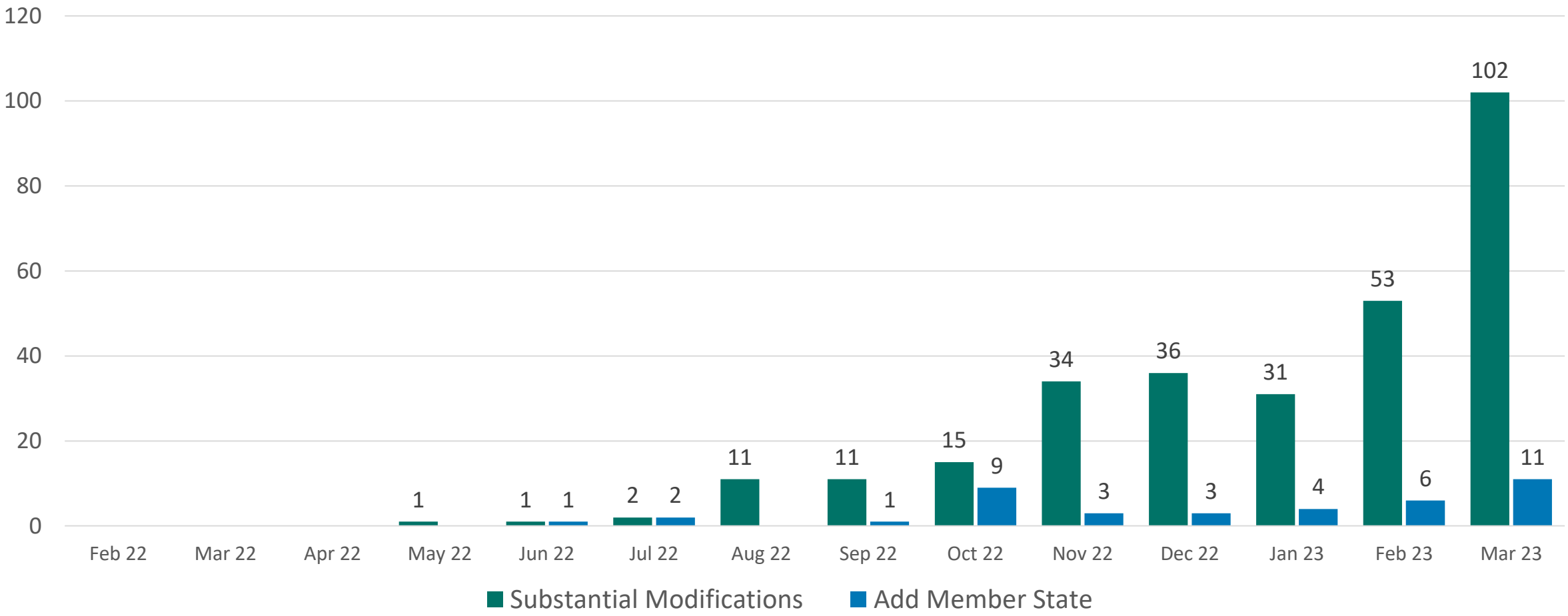
Key performance indicators (KPIs) to monitor the European clinical trials environment EMA/174654/2023 [31 Jan 2022 – 31 Mar 2023]

*CTIS Weekly Updates (cum. data)

CTIS statistics: Substantial Modifications and Add Member State Applications

31 January 2022 – 31 March 2023



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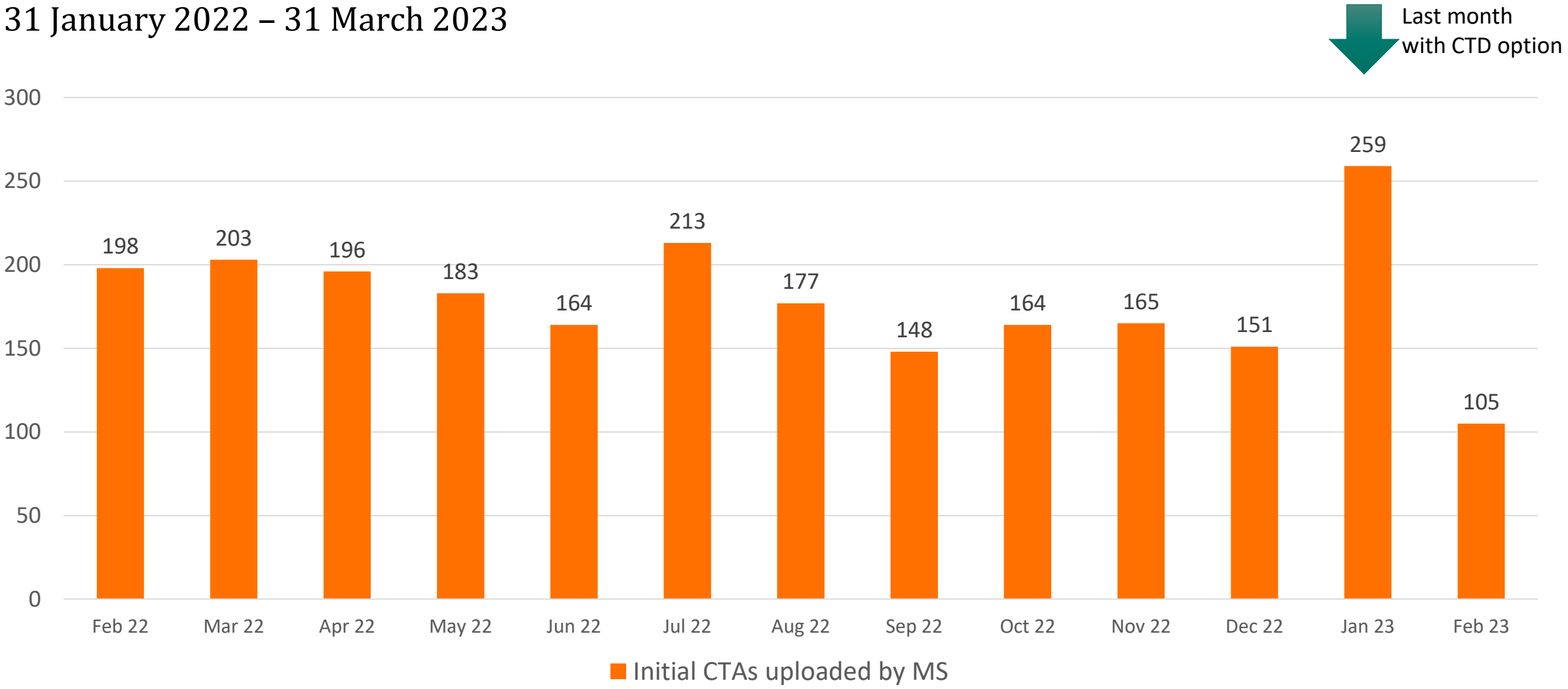
*CTIS Weekly Updates (cum. data)

EudraCT statistics: CTAs Uploads per Member State (CTAs according to CTD)

31 January 2022 – 31 March 2023



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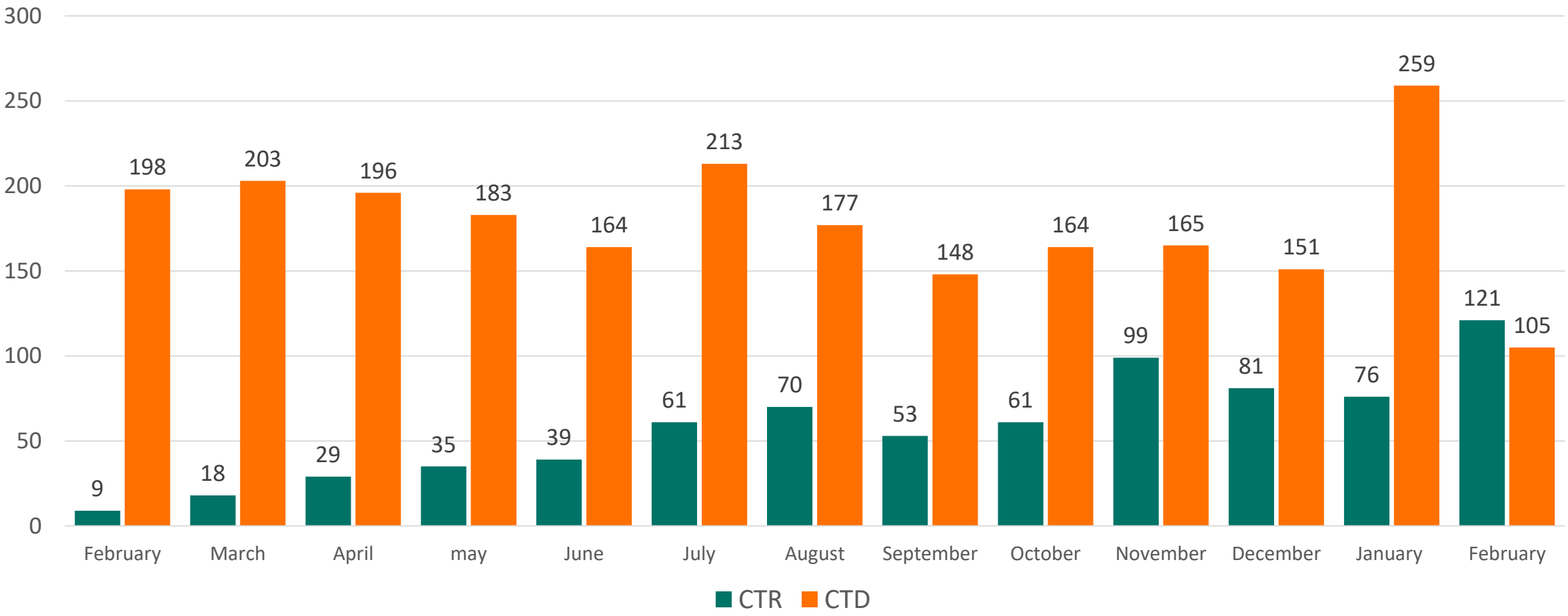
Key performance indicators (KPIs) to monitor the European clinical trials environment EMA/174654/2023 [31 Jan 2022 – 31 Mar 2023]

CTIS vs **EudraCT** metrics: CTAs submitted by CTIS vs. CTAs uploaded per Member State

31 January 2022 – 28 February 2023



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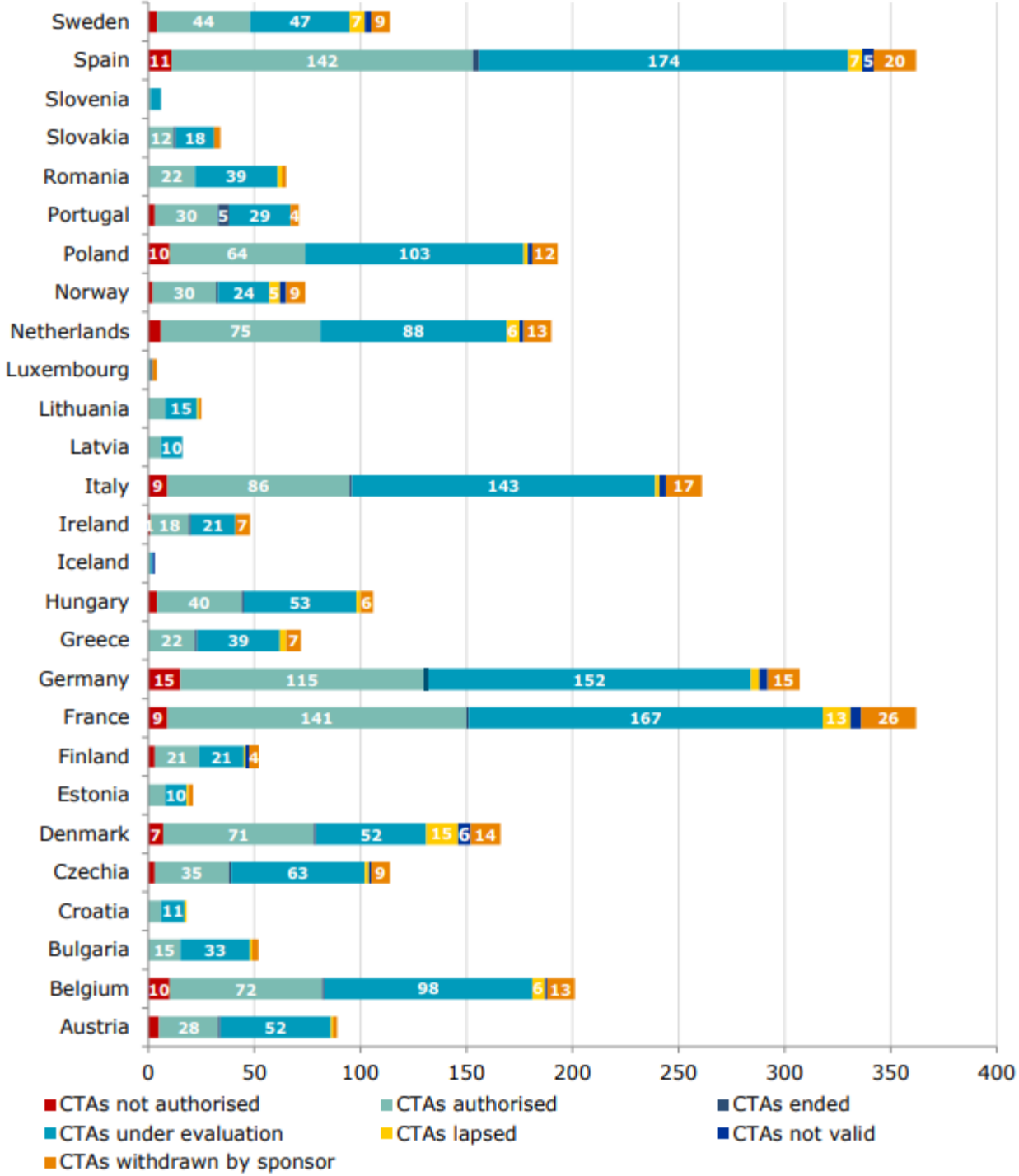
Total CTAs per Member State

31 January 2022 – 31 March 2023



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Total CTAs per Member State

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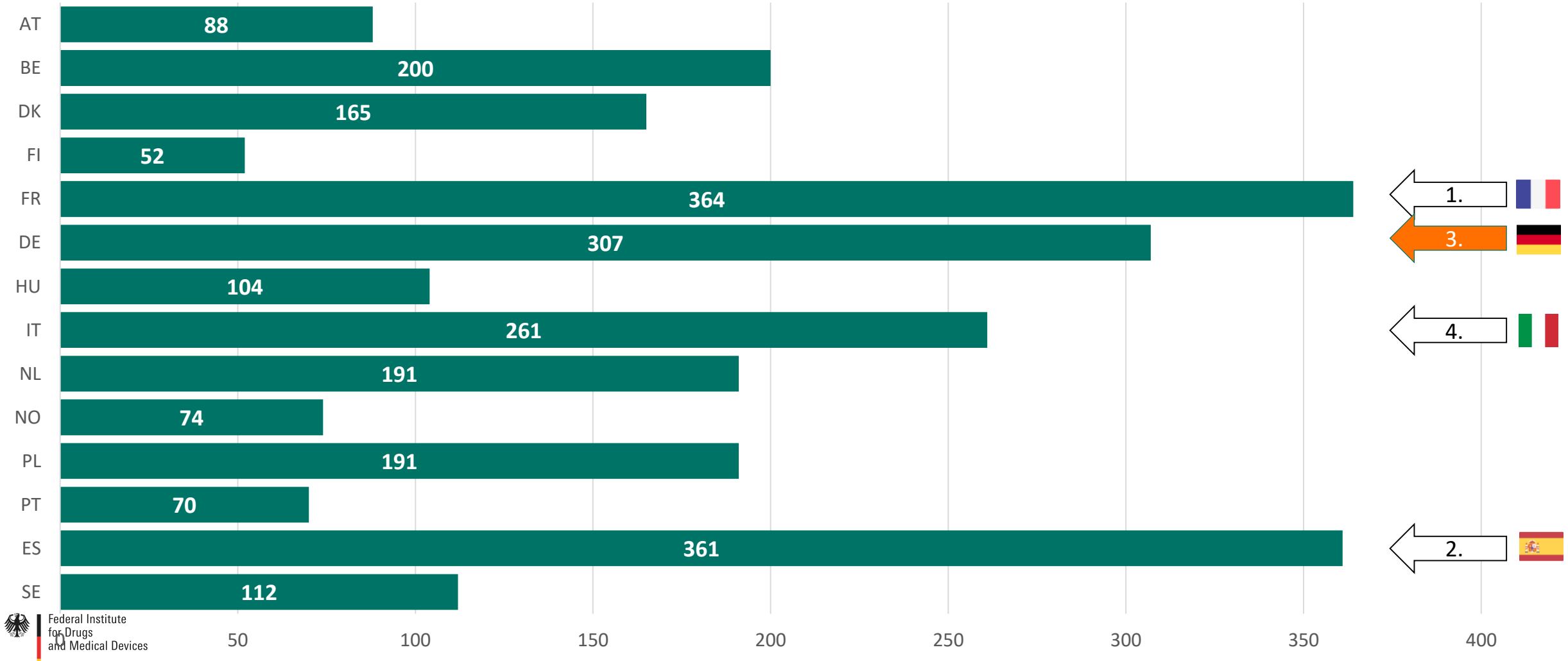

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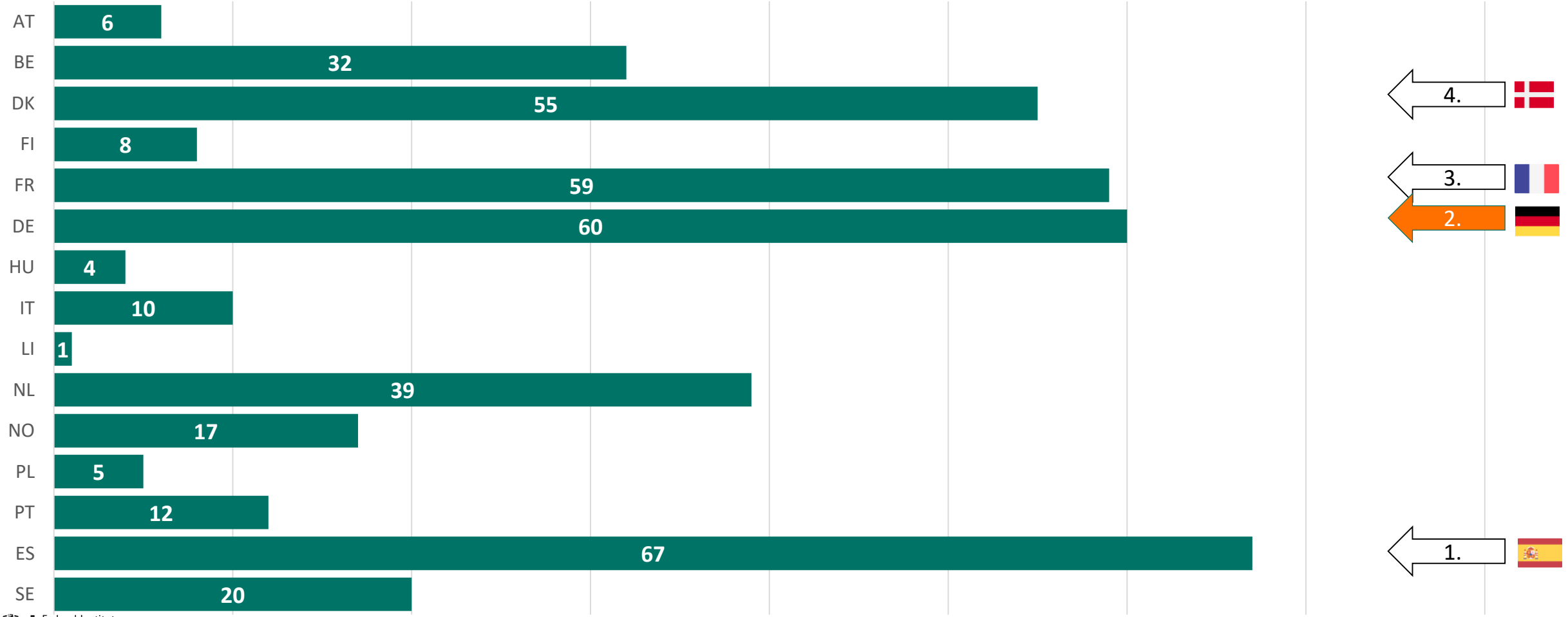
RMS-ships: Total CTAs

31 Jan 2022 – 31 Mar 2023



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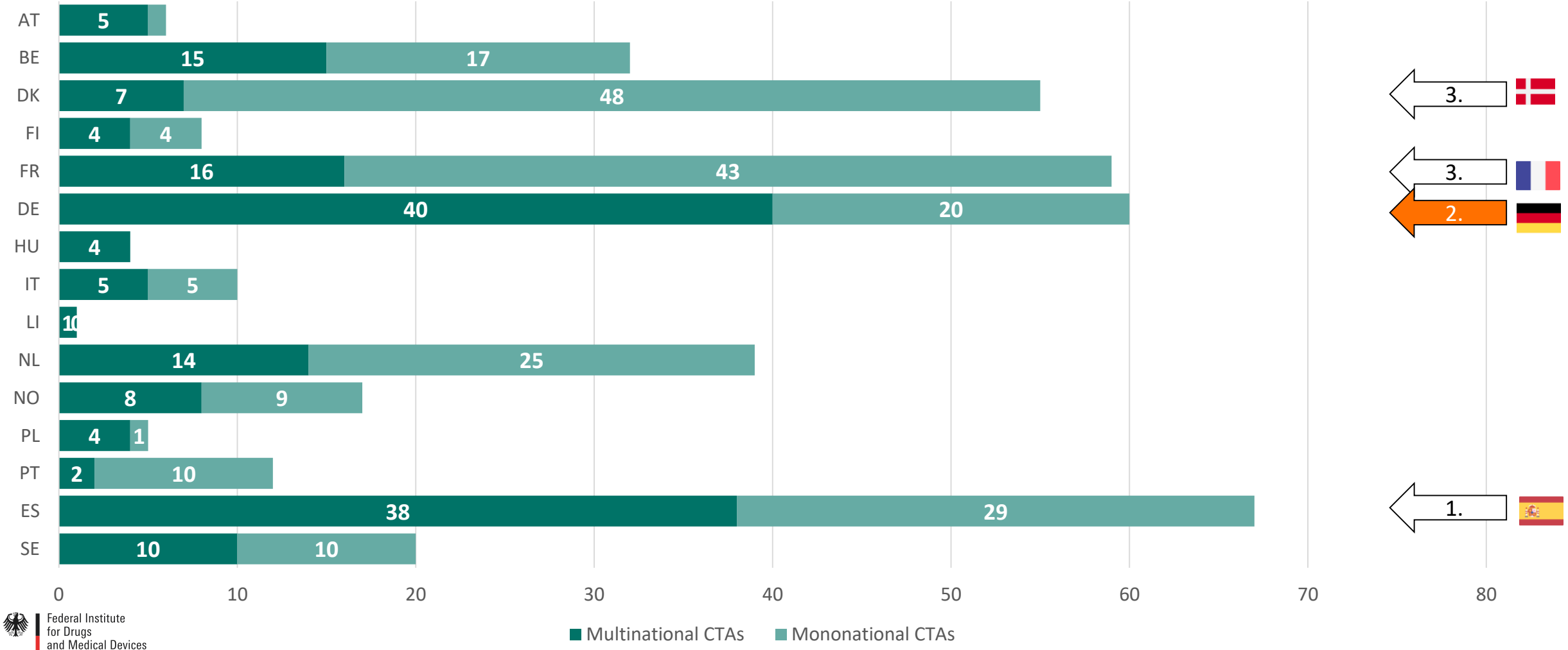
Key performance indicators (KPIs) to monitor the European clinical trials environment EMA/174654/2023 [31 Jan 2022 – 31 Mar 2023]

RMS-ships: Multinational + Mononational CTAs

31 Jan 2022 – 31 Mar 2023



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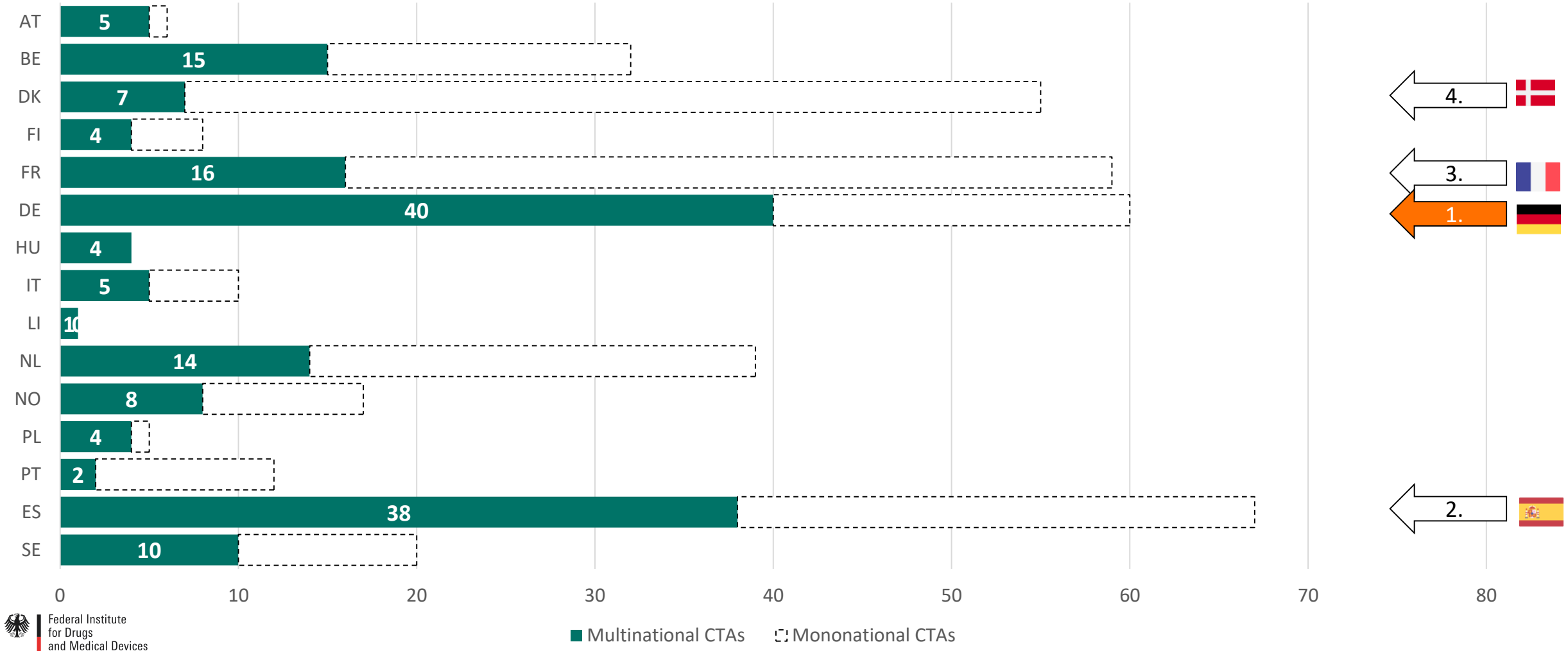
RMS-ships: Multinational CTAs

31 Jan 2022 – 31 Mar 2023



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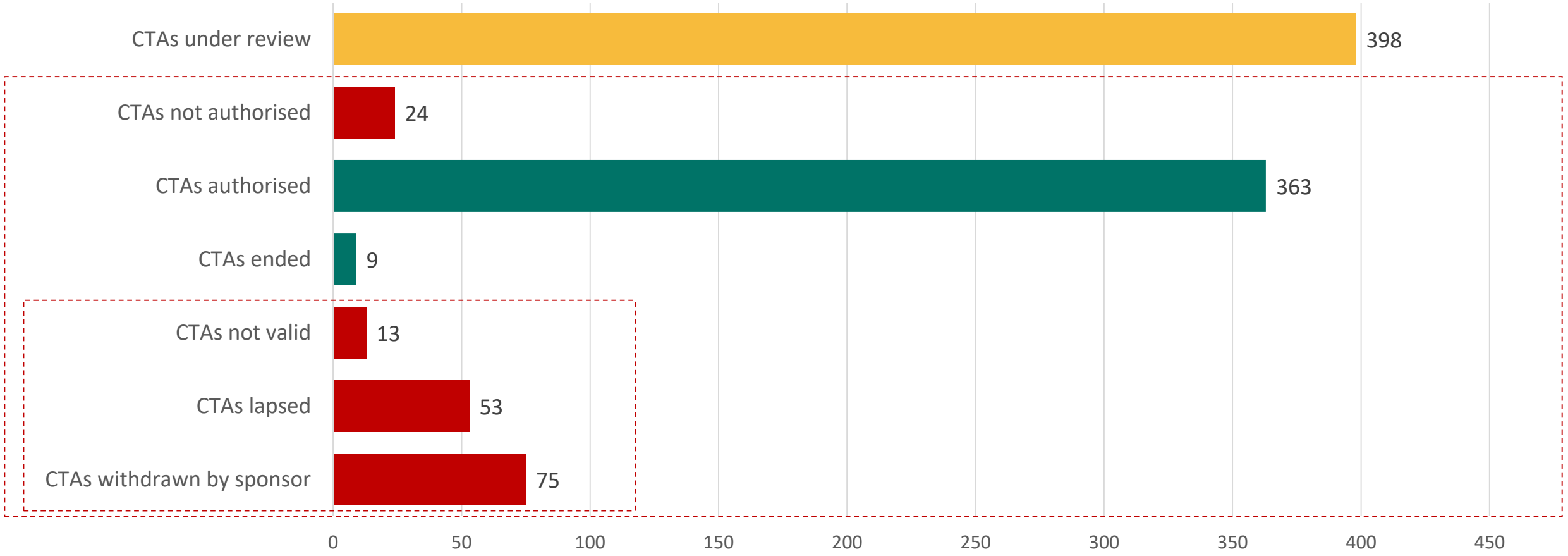
CTAs in CTIS per Status

31 Jan 2022 – 31 Mar 2023



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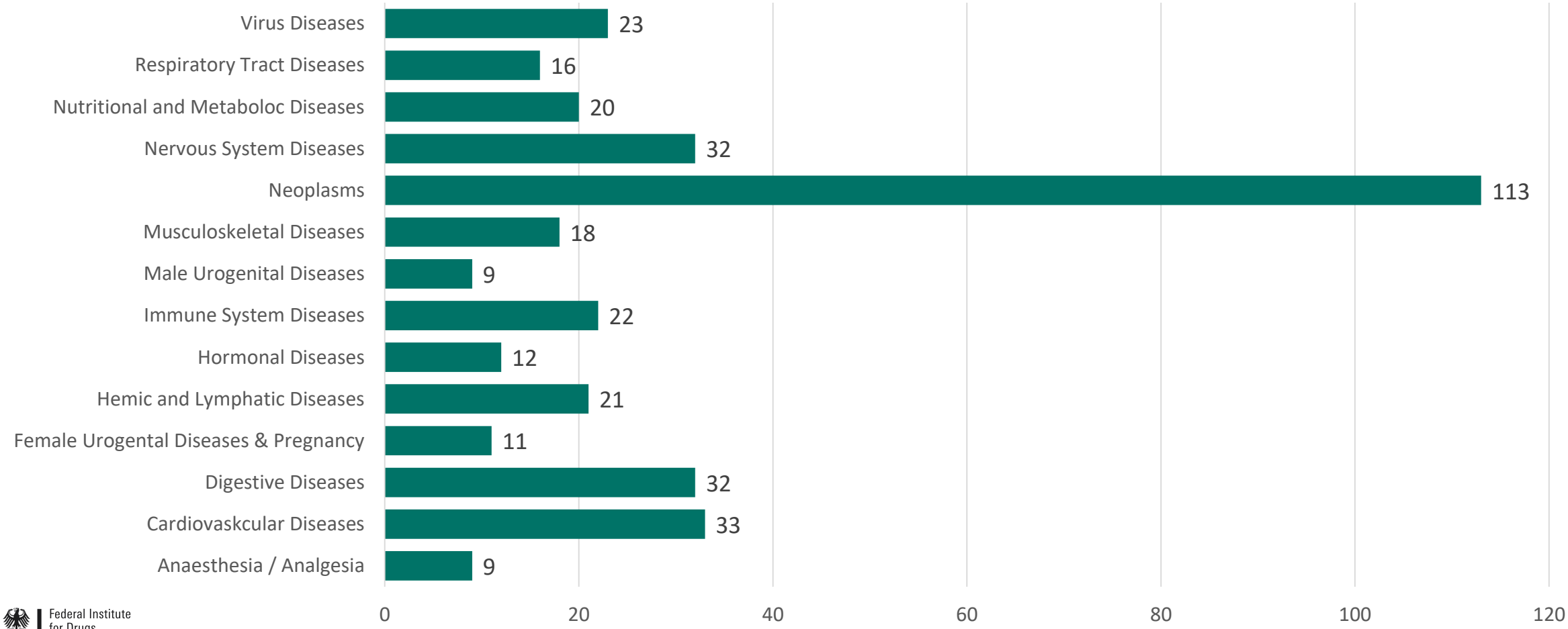
CTAs with a decision in CTIS per therapeutic area

31 Jan 2022 – 31 Mar 2023



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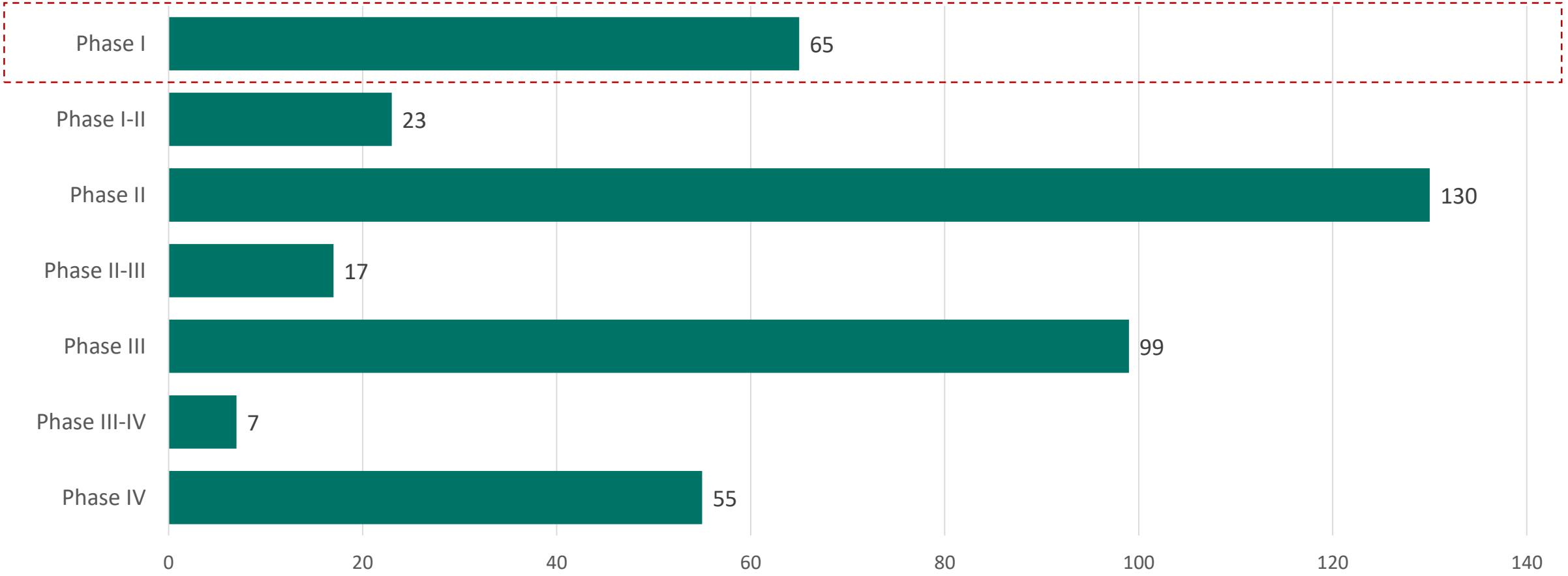
Key performance indicators (KPIs) to monitor the European clinical trials environment EMA/174654/2023 [31 Jan 2022 – 31 Mar 2023]

CTAs with a decision in CTIS per phase

31 Jan 2022 – 31 Mar 2023



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Key performance indicators (KPIs) to monitor the European clinical trials environment EMA/174654/2023 [31 Jan 2022 – 31 Mar 2023]

BfArM Commitment for mononational CTAs

The BfArM commits

- to evaluate validated applications within **26 days** and
- to make and communicate the final decision within **4 days** via CTIS

Working Group of Medical Ethics Committees (AKEK)

The board of the AKEK has also indicated that the 26-day deadline for the evaluation of Part II can also be adhered to, so that mononational clinical trials under the purview of the BfArM can be decided within 30 days after validation

Validation

For mono-centre studies, a shortening of the validation is envisaged by BfArM and AKEK

CTIS: euclinicaltrials.eu

Clinical Trials

English EN | CTIS log in

About | Search clinical trials and reports | CTIS for sponsors | CTIS for authorities | Support

All initial applications must be submitted through CTIS from **31/01/23**

Clinical trials in the European Union

This website supports the undertaking and oversight of clinical trials in the European Union (EU) and European Economic Area (EEA).

It is part of a broad initiative to transform the EU/EEA clinical trials environment in support of large clinical trials in multiple European countries, to the benefit of medical innovation and patients.

A clinical trial is a study performed to investigate the safety or efficacy of a medicine. For human medicines, these studies are carried out in human volunteers.

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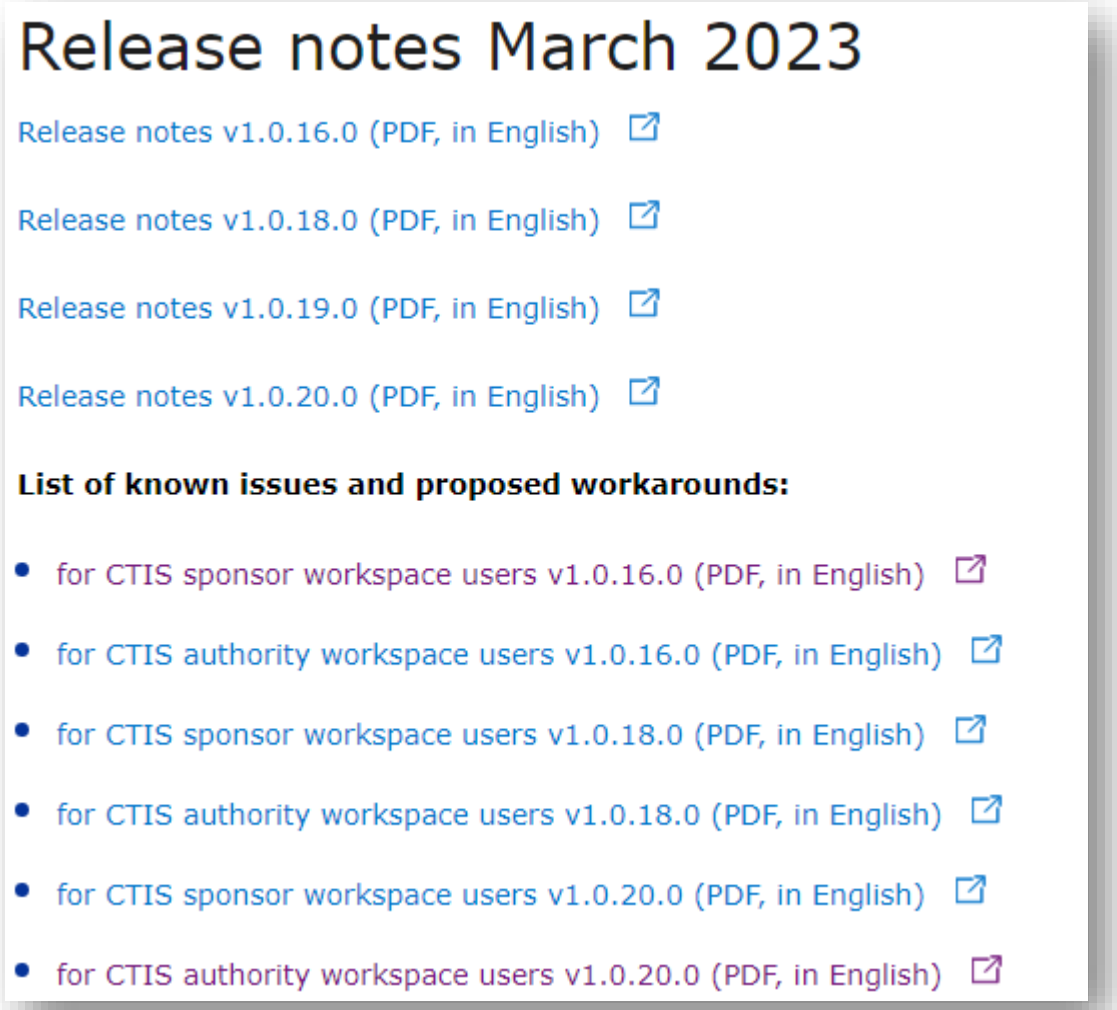
CTIS development



Release notes March 2023

Release notes v1.0.16.0 (PDF, in English)

Release notes v1.0.18.0 (PDF, in English)

Release notes v1.0.19.0 (PDF, in English)

Release notes v1.0.20.0 (PDF, in English)

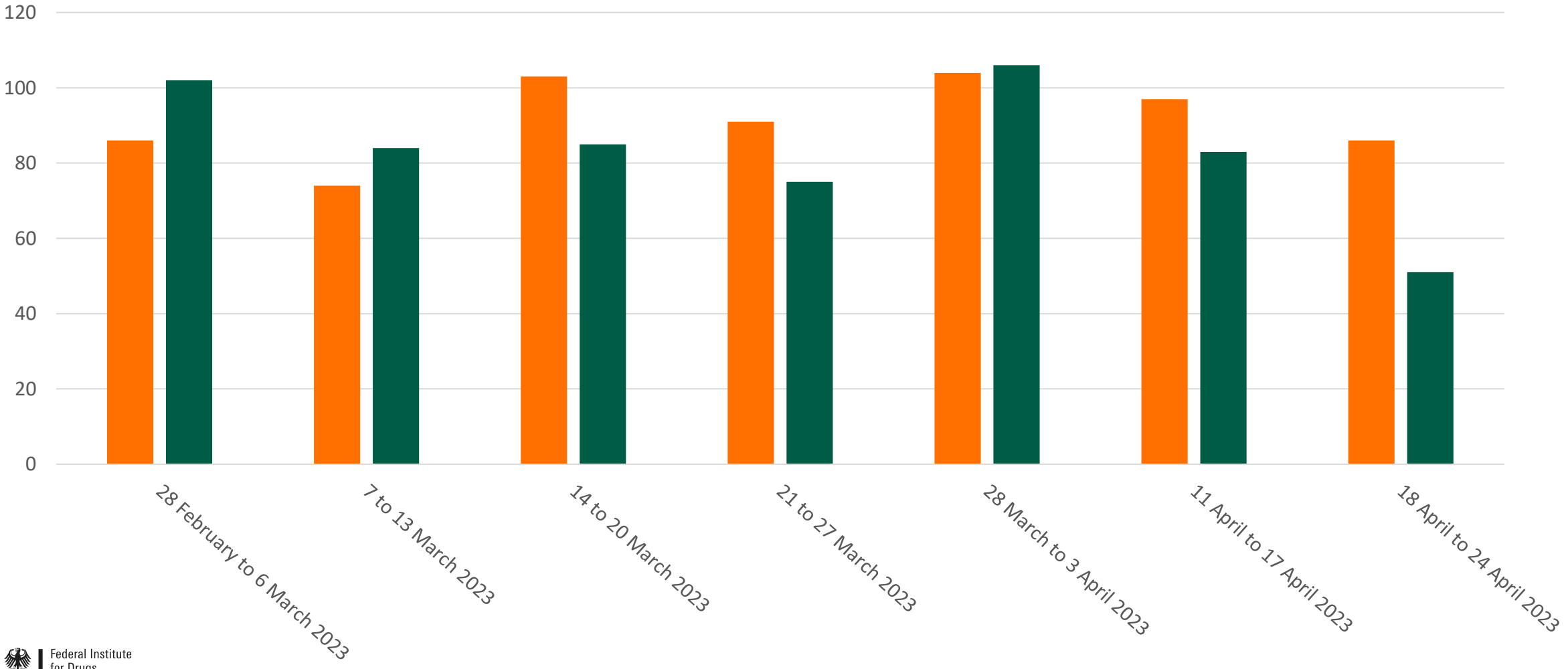
List of known issues and proposed workarounds:

- for CTIS sponsor workspace users v1.0.16.0 (PDF, in English)
- for CTIS authority workspace users v1.0.16.0 (PDF, in English)
- for CTIS sponsor workspace users v1.0.18.0 (PDF, in English)
- for CTIS authority workspace users v1.0.18.0 (PDF, in English)
- for CTIS sponsor workspace users v1.0.20.0 (PDF, in English)
- for CTIS authority workspace users v1.0.20.0 (PDF, in English)

https://euclinicaltrials.eu/website-outages-and-system-releases/

CTIS: Incidents vs resolved issues

28 Feb 2023 – *24 Apr 2023*



CTIS Weekly Updates (cum. data)

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Recent CTIS modifications/fixes

- Improvements to application creation/preparation of documents and data, enhancing the search functionality and allowing users with trial-specific roles to create subsequent CTAs
- Communication between Sponsor and MS users, with enhancements to the **notices and alerts functionality** and the selection of dates in the calendar **when submitting a second RFI in Part II**
- Improvements to the Member State application programming interface (MS API)
- Process to register CTIS as a WHO data provider initiated
- CTIS login via 2FA (MFA): 1 June 2023

Take home

Mandatory phase of the CTR successfully launched

- CTIS could successfully manage a higher workload since January 2023
- Still a huge number of CTAs under CTD has been submitted during the last 3 months up to 31 January 2023

CTIS improved and further improves over time

- But still a substantial number of new issues / incidents with increasing number of applicants in CTIS
- No clear trend at the moment

DE ranking in Member State comparison

- DE ranks at 1. - 3. position in RMS-ships and total CTA submissions
- DE moves forward in RMS-ships (1st place in the last 7 weeks)
- The share of mononational CTA submissions is relatively low

BfArM Commitment for mononational CTAs

BfArM commits

- to review validated mononational CTAs within 26 days and
- to finalise and communicate the final decision within 4 days for mononational CTAs

Thank you very much for your attention!

Contact

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Zertifikat seit 2010
audit berufundfamilie

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