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EMA/246644/2022

Key performance indicators (KPIs) to monitor the European clinical trials environment

Metrics on the Clinical Trials Regulation and Clinical Trials Directive

31 January – 30 April 2022

On the 31 January 2022 the [Clinical Trials Regulation](#) (EU) No 536/2014, hereinafter 'CTR', repealing the Clinical Trials Directive 2001/20/EC, hereinafter 'CTD', became applicable and the [Clinical Trial Information System \(CTIS\)](#) was launched. In line with the provisions outlined in Article 97 of the Clinical Trials Regulation, the European Commission shall assess the impact of the Regulation on scientific and technological progress.

This report provides an overview of Key Performance Indicators (KPIs) related to the implementation of the CTR. The Clinical Trials Regulation Metrics report is published on a monthly basis starting in May 2022.

This report is published as part of the business change programme Accelerating Clinical Trials EU (ACT EU), involving the European Commission, the Heads of Medicines Agencies (HMA), Clinical Trial Coordination Group (CTCG) and the Agency.

ACT EU seeks to transform how clinical trials are initiated, designed and run. One of the priority actions of ACT EU focusses on monitoring the implementation of the CTR.

The metrics presented below reflect the status of applications in CTIS and EudraCT¹ as of 2 May 2022 for Clinical Trial applications (CTA) submitted between 31 January 2022 and 30 April 2022².

¹ EudraCT is the (European Union Drug Regulating Authorities Clinical Trials Database) European database for all interventional clinical trials on medicinal products authorised in the European Union (EEA) under the Clinical Trial Directive and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP)

² The two 'smoke test' trials, submitted to CTIS for testing purposes just before the CTIS launch, are not counted.

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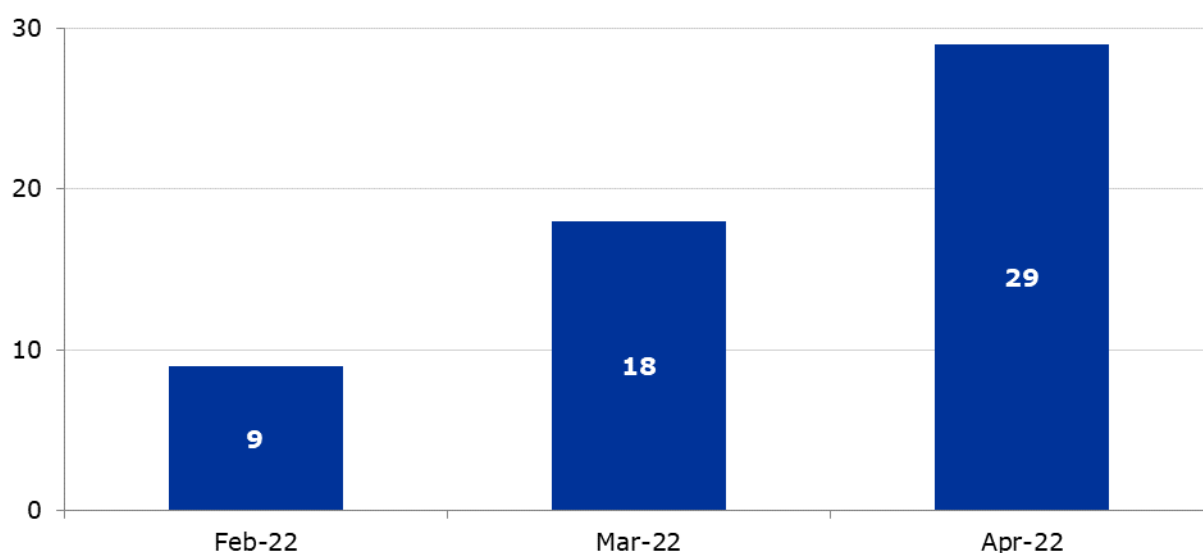
1. Clinical Trial Information System (CTIS) and EudraCT metrics

This report shows the key performance indicators (KPIs) generated from the two databases containing information on clinical trials in the EU/EEA, namely CTIS and EudraCT.

1.1. Number of clinical trial applications (CTAs) submitted under the Clinical Trials Regulation in CTIS

The graph below shows the number of clinical trial applications (equal to the number of the clinical trials during the selected period) that have been submitted to CTIS. The applications submitted are all initial clinical trial applications³.

CTAs submitted in CTIS



Overall, 56 clinical trial applications have been submitted in CTIS during the first 3 months since the launch of the system on 31st January 2022.

Of the submitted applications 3 are re-submissions of previous applications, following 2 withdrawn and 1 lapsed applications.

1.2. CTAs under Clinical Trial Directive (CTD) uploaded by Member States (MSs) in EudraCT, counted as individual clinical trial protocol

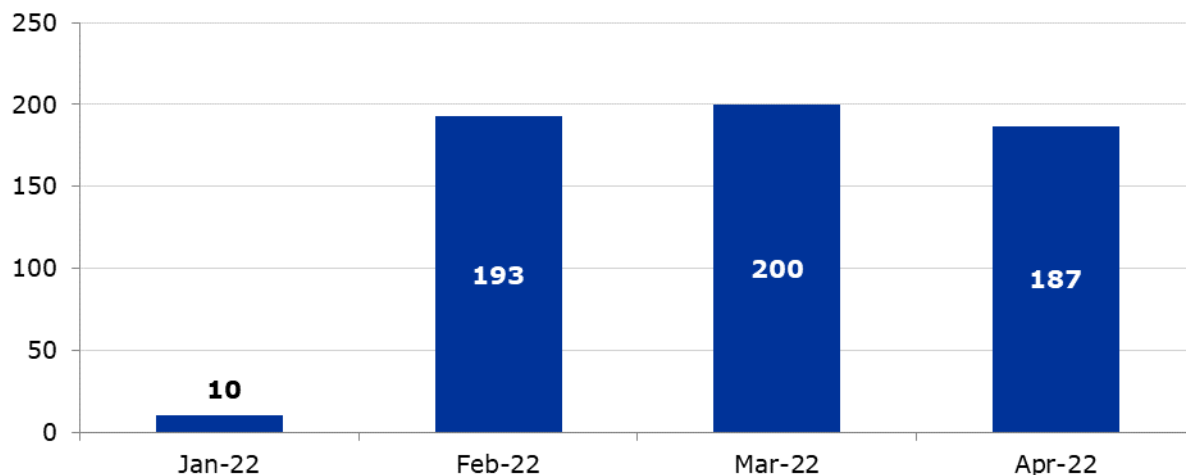
The graph below shows the number of CTAs uploaded by the Member States in EudraCT as individual clinical trial protocol⁴, per month during the selected period⁵.

³ Initial clinical trials applications are those submitted in accordance with the requirements of Article 5 and Article 11, as applicable, of the Clinical Trials Regulation (EU) No 536/2014

⁴ The figures presented below are based on distinct counts of CTA, if the same protocol is submitted to more than one MSC is counted once.

⁵ The data for January that appear in the graph below refers to CTA uploaded by the Member State on the 31st January only

CTAs uploaded by Member States in EudraCT (CTAs are counted as individual trial protocol)



1.3. Number of ongoing clinical trials (CTs)

CTs under the CTR with at least one positive decision in the EU

The term 'ongoing' refers to clinical trials that have been authorised in at least one Member State Concerned where the recruitment of patients has started at the clinical investigator sites⁶.

There were no reported clinical trials ongoing in CTIS as of 2nd May 2022.

CTs under the CTD

In EudraCT there are no fields available to capture recruitment status at the site.

1.4. Number of trials for which a decision has been issued under the CTR with/without deferral⁷ for the protocol

There were no trials for which a decision has been issued with deferrals⁸ of the protocols. All the trials with a decision have published protocols.

1.5. Number of mononational-multinational trials for which a decision has been issued by the Member States Concerned (MSC) under the Clinical Trials Regulation, broken down per sponsor type (commercial vs. non-commercial) and average number of MSCs⁹

The graph below shows the number of trials for which a decision has been issued in CTIS by the Member State Concerned, per month, since 31 January 2022. The trials reflected in the graph below have all been authorised.

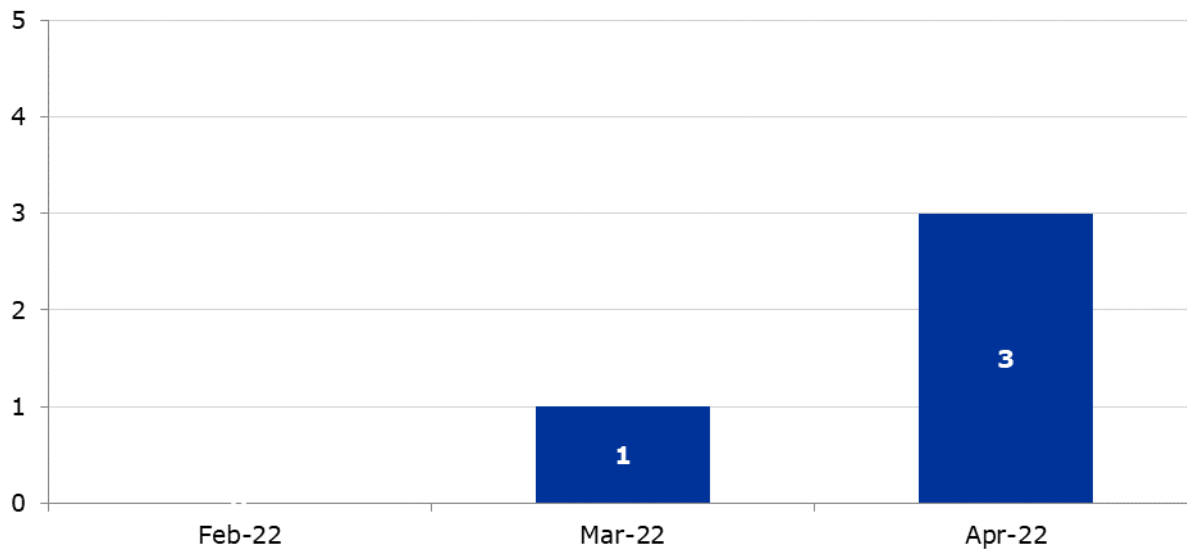
⁶ Details on recruitment status are based on the information reported by the trial sponsor in CTIS

⁷ The option to defer the protocol is only available in CTIS.

⁸ Deferral is a functionality implemented in CTIS that has been introduced to reduce the burden of redaction of commercially confidential information (CCI) in the documents uploaded in CTIS. More information on deferrals can be found in the [Appendix on disclosure rules](#)

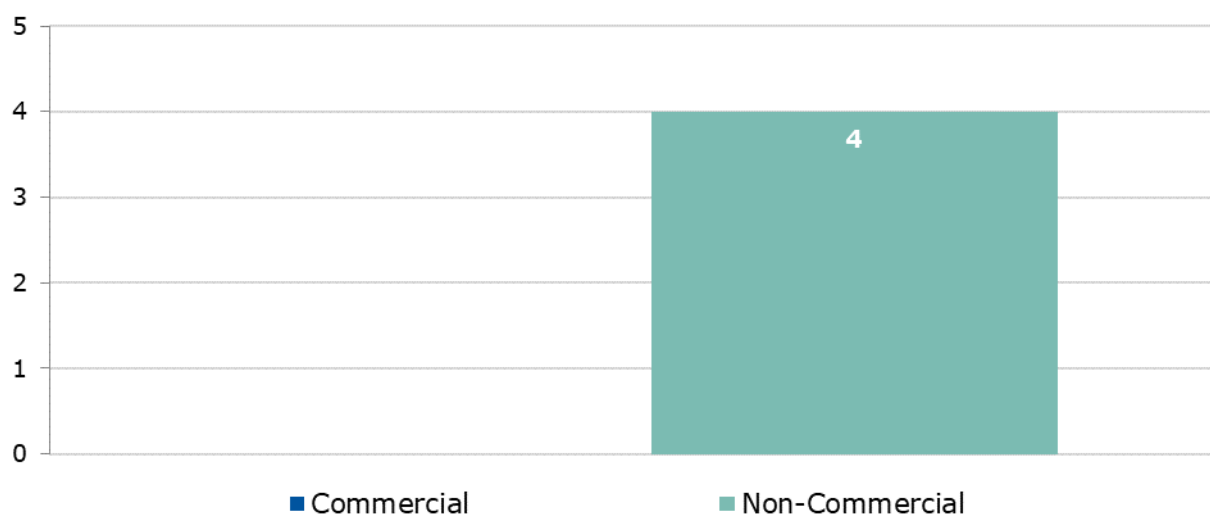
⁹ The information on trial sponsor type: commercial vs non-commercial is derived from OMS: Organisation Management Service database, and it is not recorded as such in the clinical trial application form

CTs with a decision in CTIS



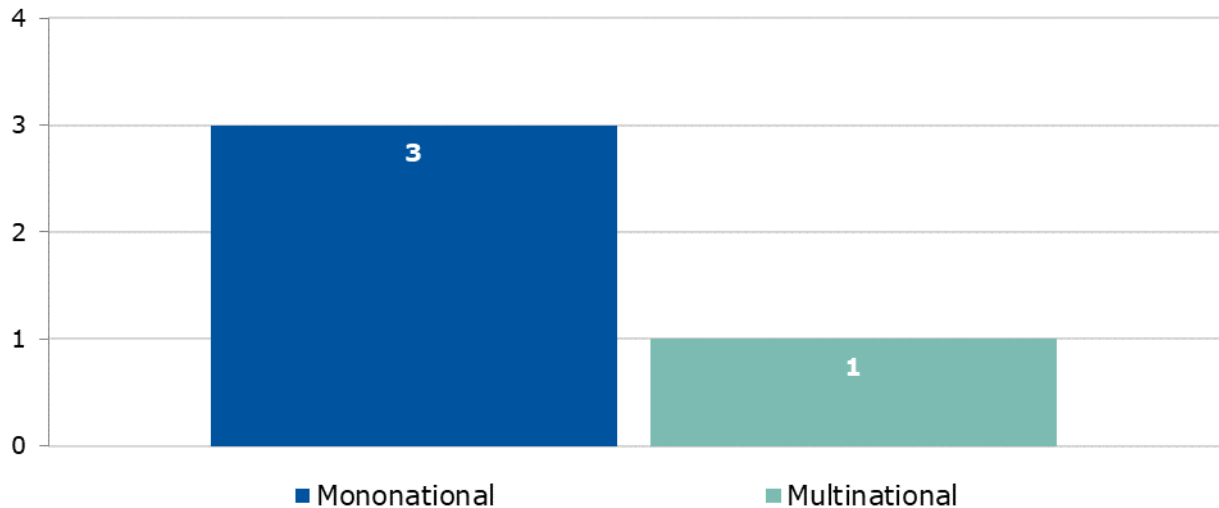
The graph below shows the number of trials for which a decision has been issued in CTIS by the Member States Concerned, broken down by sponsor type.

CTs with a decision in CTIS Commercial versus Non-Commercial



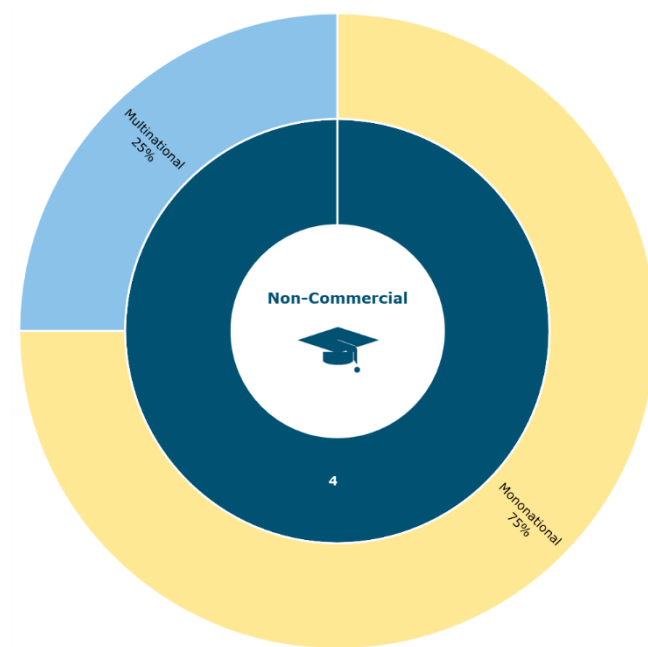
The graph below shows the number of trials for which a decision has been issued in CTIS by the Member States Concerned, broken down whether the trial is a mono- or multinational.

CTs with a decision in CTIS Mononational versus Multinational



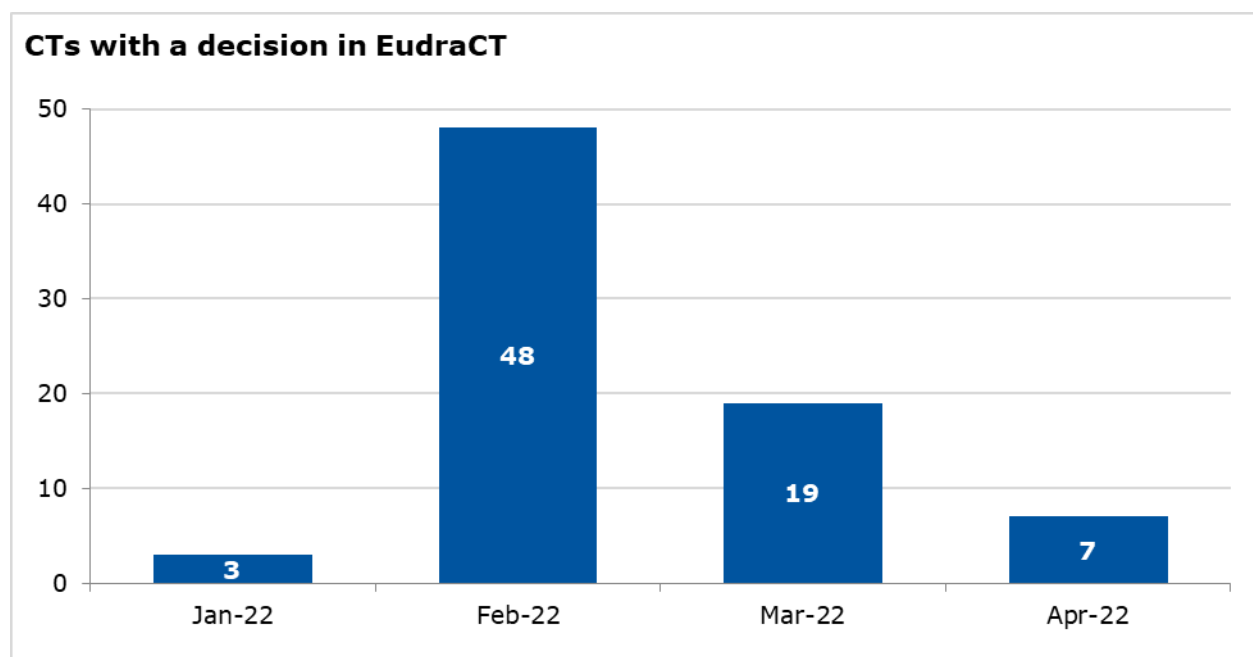
Currently one multinational clinical trial has a decision (authorised) in CTIS with 14 Member States Concerned. An average will be provided in future reports when more than one multinational trial has a decision recorded.

The graph below shows the number of clinical trials for which a decision has been issued, with information whether the trial is a mono- or multinational and in relation to sponsor type.



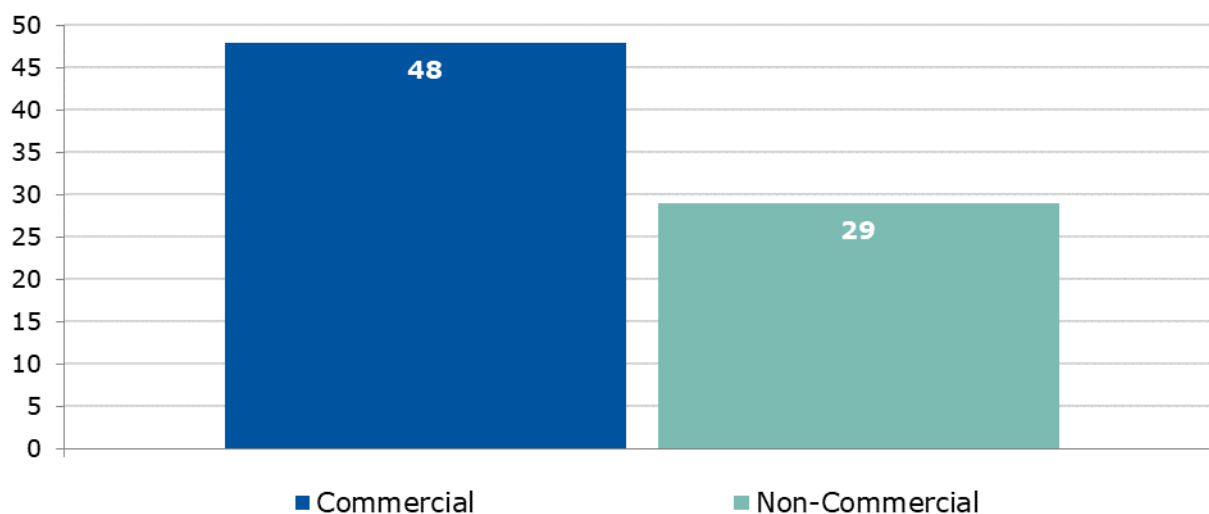
1.6. Number of mononational-multinational trials for which a decision has been issued by the Member States under the Clinical Trials Directive, broken down per sponsor type (commercial vs. non-commercial) and average number of MSs

The graph below shows the number of trials that received a National Competent Authority decision and an Ethics Committee opinion from the Member States, per month, since 31 January 2022. The trials reflected in the graph below have all been authorised¹⁰.



The graph below shows the number of trials for which a decision has been issued by the Member States in EudraCT broken down by sponsor type.

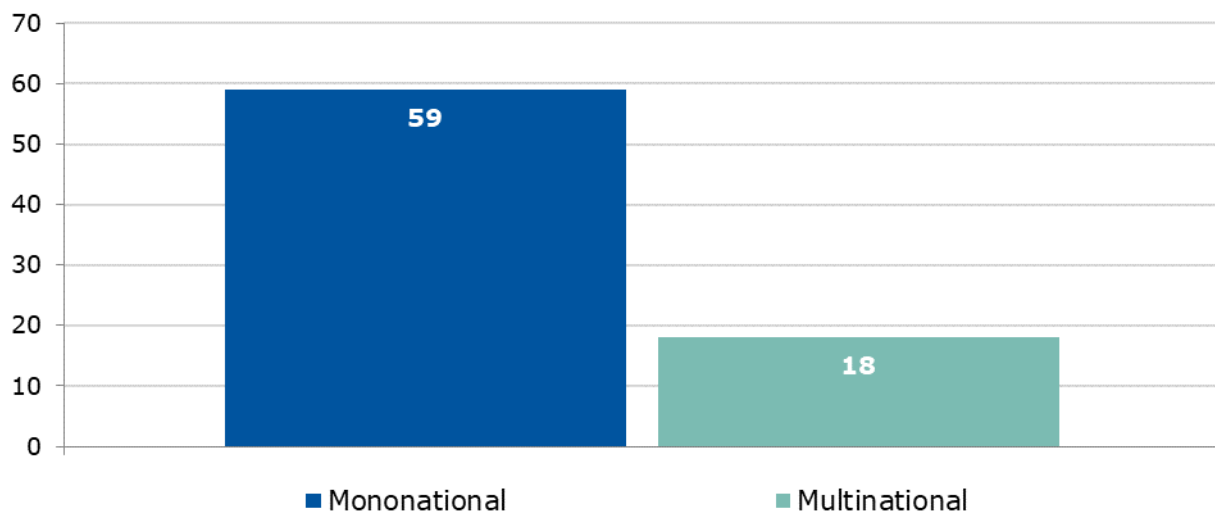
**CTs with a decision in EudraCT
Commercial versus Non-Commercial**



¹⁰ The data for January that appear in the graph below refers to CTA authorised by the Member State on the 31st January only.

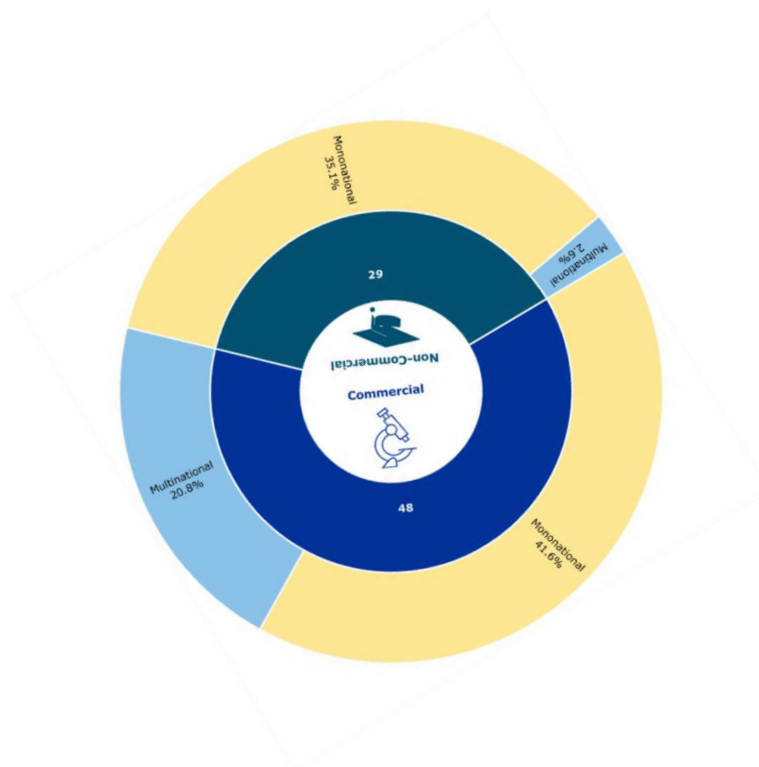
The graph below shows the number of trials for which a decision has been issued by the Member States in EudraCT broken down whether the trial is a mononational or multinational trials.

CTs with a decision in EudraCT Mononational versus Multinational



Considering clinical trials for which a decision has been issued, on average 2 Member States are involved in multinational trials.

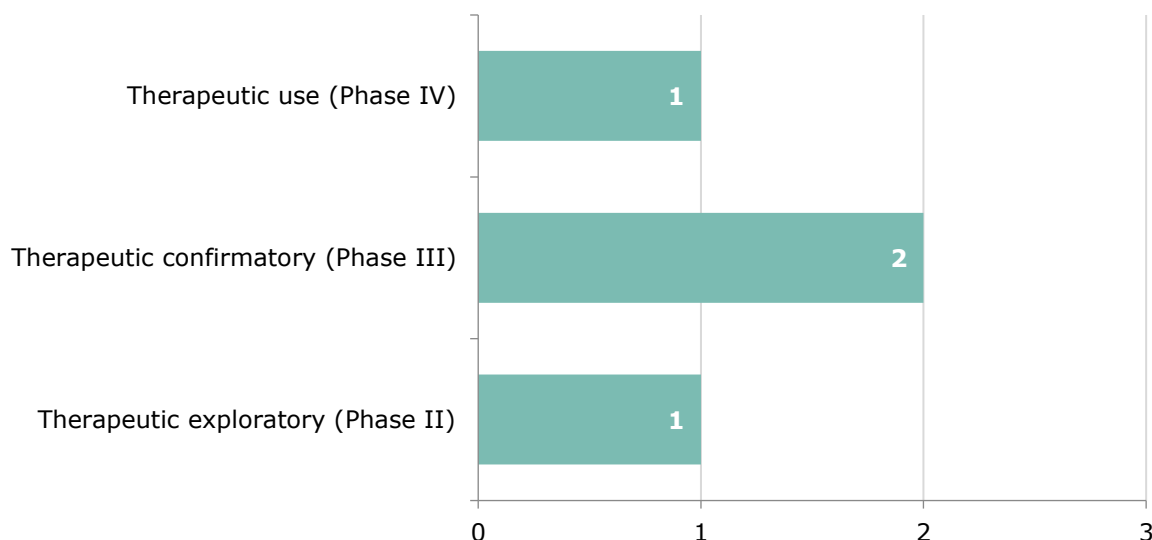
The graph below shows the number of clinical trials for which a decision has been issued, with information whether the trial is a mono- or multinational and in relation to sponsor type.



1.7. Number of clinical trials for which a decision has been issued per phase (i.e. I, II, III, IV, as well as CT first in human or combined phases early (I and II)) under CTR¹¹

The graph below shows the number of clinical trials for which a decision has been issued, broken down per trial phase.

CTs with a decision in CTIS per phase



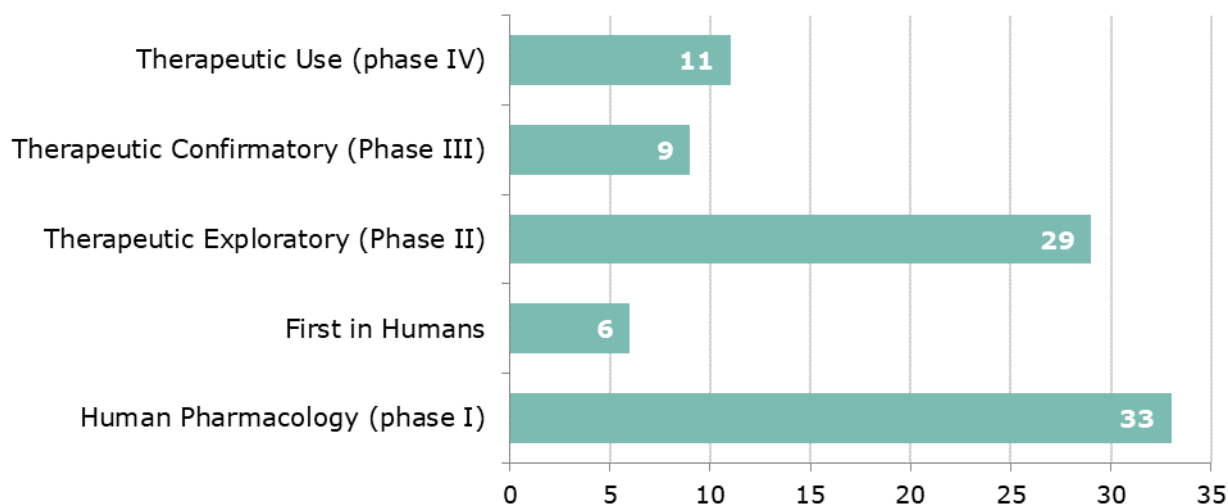
Number of clinical trials for which a decision has been issued per phase (i.e. I, II, III, IV, as well as CT first in human or combined phases early (I and II)) under CTD¹²

The graph below shows the number of clinical trials, as individual clinical trial protocol, for which a decision has been issued by the Member States in EudraCT broken down per trial phase.

¹¹ More than one trial phase can be selected for a single trial and it is counted in each trial. The graph shows only the applicable trial phases for the authorised trials in the selected period.

¹² More than one trial phase can be selected for a single trial and it is counted in each trial. The graph shows only the applicable trial phases for the authorised trials in the selected period.

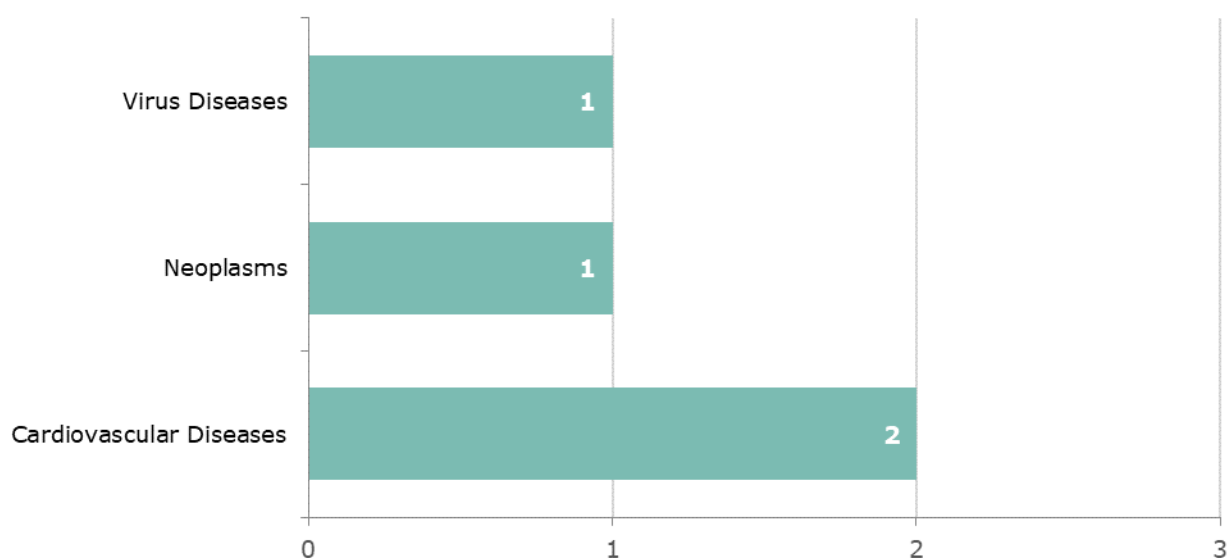
CTs with a decision in EudraCT per phase



1.8. Number of trials for which a decision has been issued under CTR, per therapeutic area¹³

The graph below shows the number of clinical trials for which a decision has been issued in CTIS, broken down per therapeutic area.

CTs with a decision in CTIS per therapeutic area

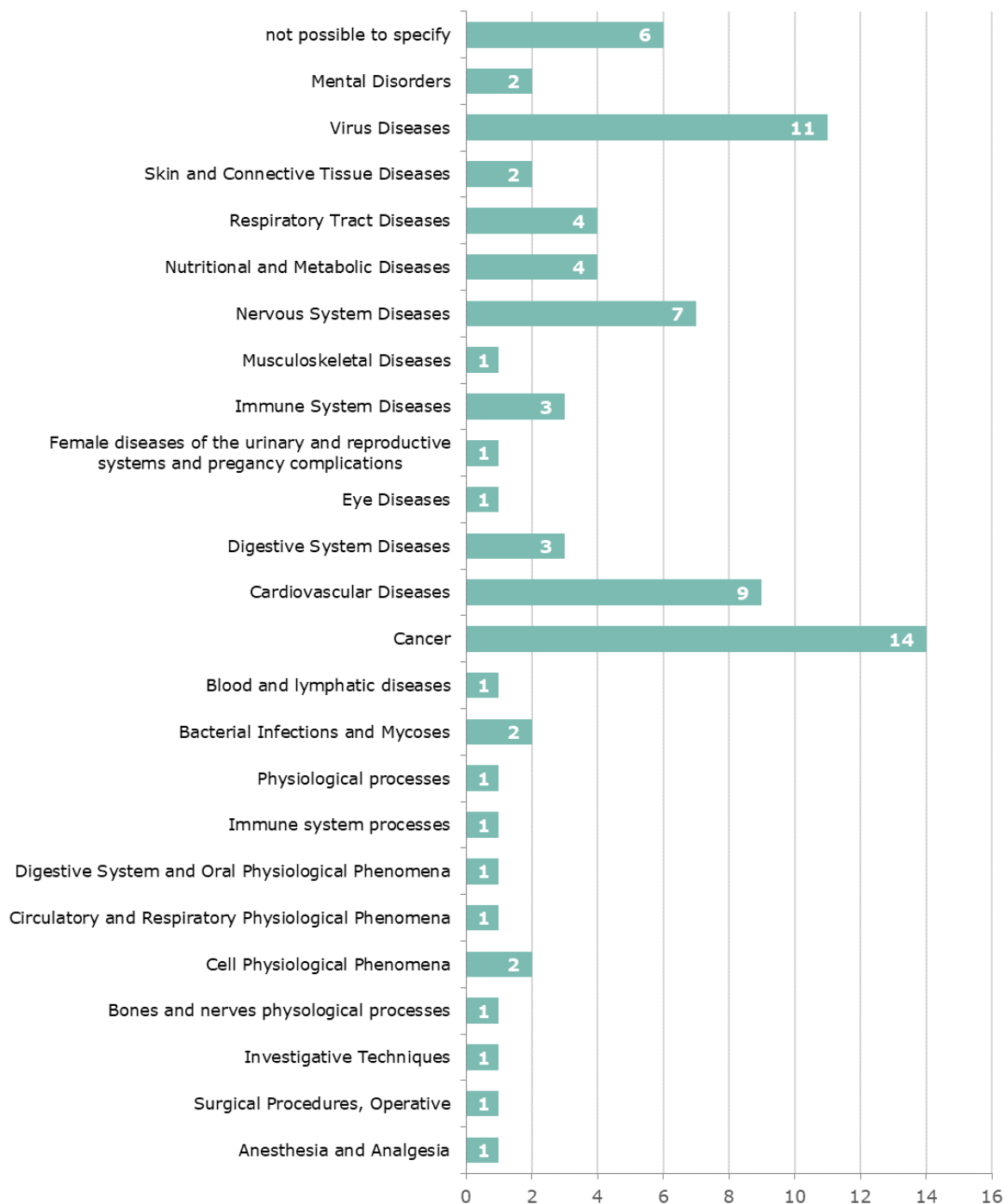


¹³ More than one therapeutic area can be selected for a single trial and it is counted in each trial. The graph shows only the applicable therapeutic areas for the authorised trials in the selected period.

1.9. Number of trials for which a decision has been issued under CTD, per therapeutic area¹⁴

The graph below shows the number of trials, as individual clinical trial protocol, for which a decision has been issued by the Member States in EudraCT broken down per therapeutic area.

CTs with a decision in EudraCT per therapeutic area



1.10. Number of trials for which a decision has been issued on Advanced Therapy Medicinal Products (ATMP) under CTR

None of the clinical trials for which a decision has been issued in CTIS during the selected period includes an Advance Therapy Medicinal Product.

1.11. Number of trials for which a decision has been issued, with ATMP of type "gene therapy", "somatic cell therapy" and "tissue engineered therapy" under CTR

None of the clinical trials for which a decision has been issued in CTIS during the selected period includes an Advance Therapy Medicinal Product of type: gene therapy, somatic cell therapy and tissue engineered therapy.

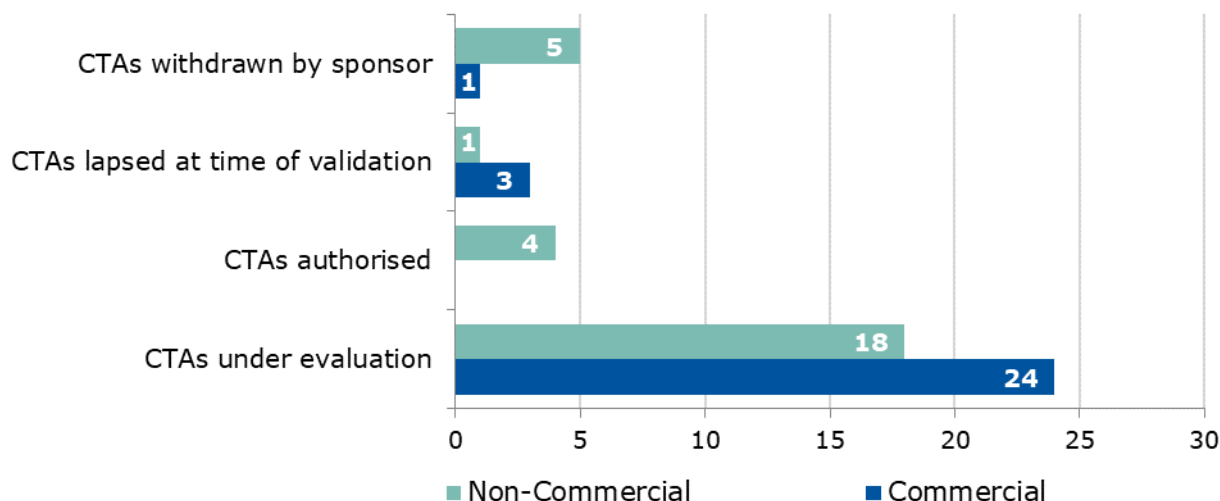
1.12. Number of trials for which a decision has been issued, with ATMP of type "gene therapy", "somatic cell therapy" and "tissue engineered therapy" under CTD.

There were two clinical trials with a decision (authorised) during the selected period including an advanced therapy medicinal product, both of them on a gene therapy product.

1.13. Number of clinical trial applications under the CTR per applicable trial status during the selected period, broken down per sponsor type: non- commercial/commercial

The graph below shows the number of initial clinical trial applications, per applicable trial status and information of sponsor type.

**CTAs per Trial status in CTIS
Commercial versus Non-Commercial**



Art 14 applications: (re-)submission, authorisation, rejection, lapsed and withdrawn dossiers

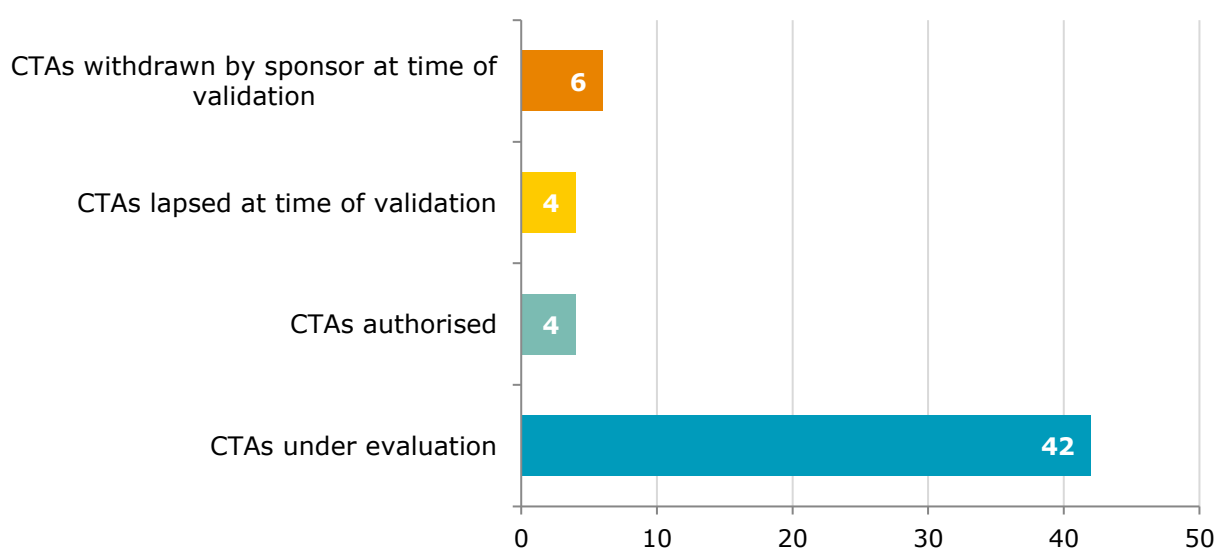
¹⁴ It should be noted that more than one therapeutic area can be selected for a single trial and it is counted in each trial. The graph shows only the applicable therapeutic areas for the authorised trials in the selected period.

There are no applications in CTIS for the addition of a new MSC foreseen under Article 14 of Regulation (EU) No 536/2014.

1.14. Number of CTAs Article 5 of CTR [full dossier initial applications] per applicable trial status during the reporting period, at EU, at MS level and with Reporting Member State (RMS) details

The graph below shows the number of initial clinical trial applications with full dossier, submitted in accordance with Article 5 of CTR, per applicable status at EU level.

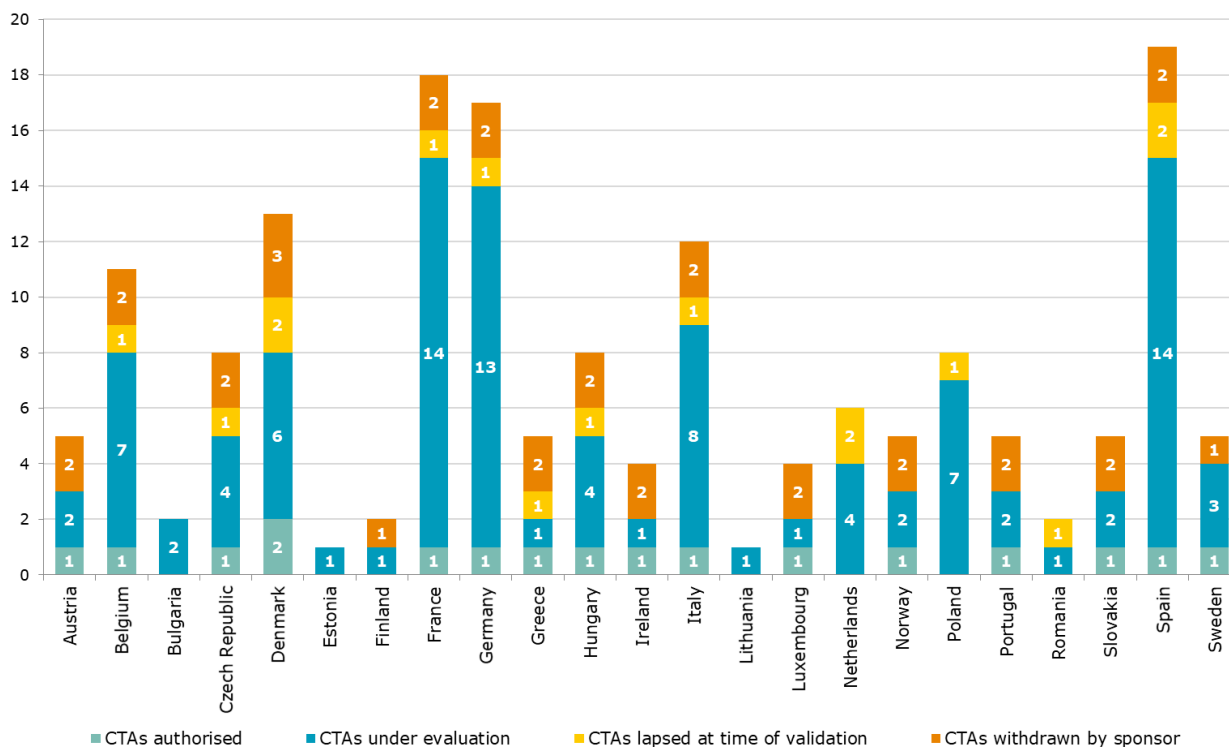
CTAs in CTIS per Status



The graph below shows the number of initial clinical trial applications with full dossier, submitted in accordance with Article 5 of CTR, per applicable status at the level of the Member States Concerned¹⁵.

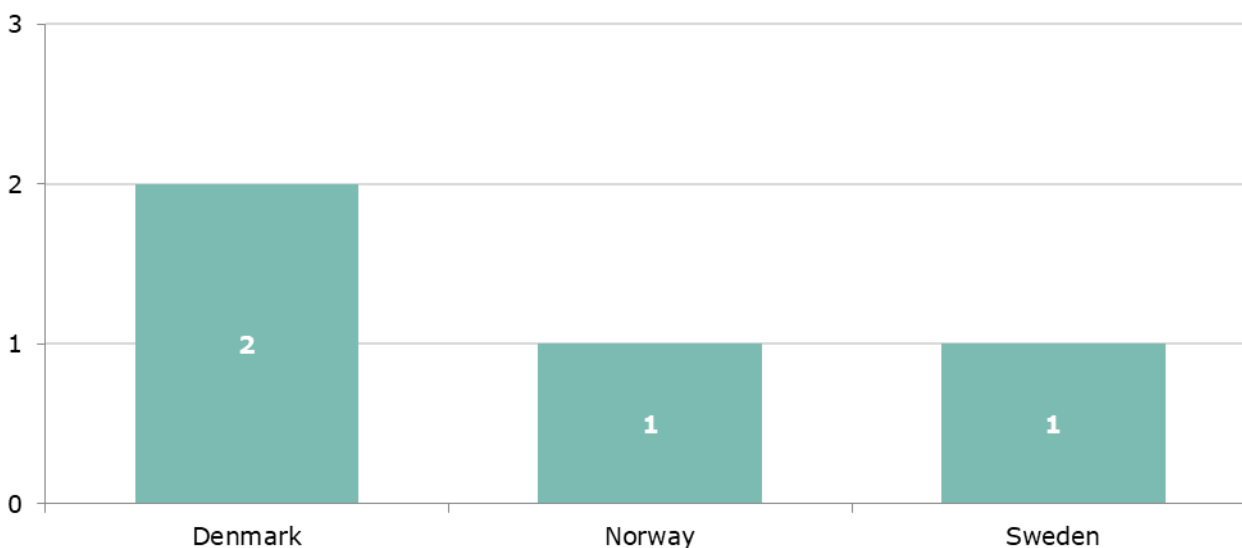
¹⁵ In multinational clinical trials the same application has been submitted to multiple Member State Concerned, and it is counted in the graph in each applicable MSC.

Member States Concerned



The graph below shows the distribution of appointment of Reporting Member State (RMS)¹⁶, amongst the applicable Member States Concerned, for clinical trial applications on which a decision has been issued.

Reporting Member State



¹⁶ RMS is the Reporting Member State appointed in line with the requirements of Article 5 of the Clinical Trials Regulation (EU) No 536/2014

1.15. Number of CTAs Article 11 of CTR [partial dossier initial applications with later Part II submission] per applicable trial status during the reporting period, at EU and at MS level

Partial initial applications submitted to CTIS in line with the requirements of Article 11 of the Regulation (EU) No 536/2014 will be considered for future reporting.

1.16. Average time from submission to reporting date¹⁷ (Article 11 and Article 5 of CTR), and to first decision (Article 5 of CTR) for initial applications and Substantial Modifications part I or part I and II

The table below shows the number of calendar days since the submission of the initial clinical trial application to CTIS up to the time of the first decision of the Member States Concerned.

Submission date	Decision date	Days to Decision
9 February 2022	7 April 2022	57
15 February 2022	27 April 2022	71
28 February 2022	28 March 2022	28
15 March 2022	27 April 2022	43

On average it took 50 calendar days from submission to decision for the 4 authorised initial CTAs.

1.17. Number of submitted, validated, authorised, rejected, lapsed and withdrawn Substantial Modification (SM) applications, related to part I / II / I and II, by sponsor type

There are no applications in CTIS related to submission of substantial modification part I only, part II only or part I and part II as foreseen in Chapter II of the Regulation (EU) No 536/2014.

1.18. Number of active substances (ASs) in CTR EU trials (mononational and multinational AS)

KPI on the number of active substances (also linked with KPI 16 on saMS selection) will be considered for future reporting.

1.19. Number of safety assessing Member State (saMS)-ships per MS

The safety assessing Member State Concerned (saMS) will be The safety assessing Member State Concerned (saMS) will be applicable for the multinational clinical trials. No saMS have been appointed during the selected period.

¹⁷ The reporting date is equal to the date of the RMS conclusion on part I assessment