European Commission

EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

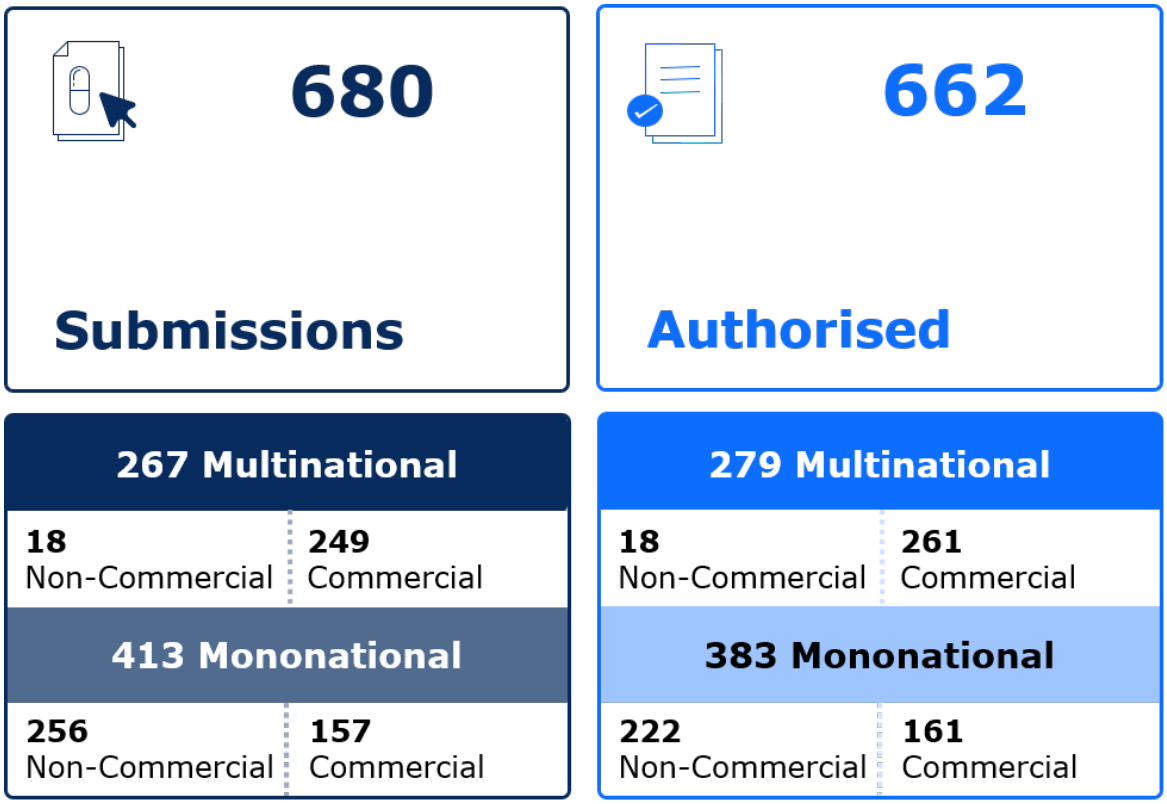
Monitoring the European clinical trials environment

April-June 2026

An agency of the European Union

Clinical Trials in the EU/EEA

April-June 2026



The metrics in this report provide information on the trend of the clinical research environment in the European Union (EU) and European Economic Area (EEA). The numbers used are based on data retrieved from the Clinical Trials Information System (CTIS) for clinical trials regulated under the regime of the Clinical Trials Regulation (EU) No 536/2014 (CTR).

The data set for this report shows data for the months April-June 2026, as of 30 June 2026, as well as cumulative numbers since the launch of CTIS on 31 January 2022. According to Article 98 of the Clinical Trials Regulation (EU) 536/2014, the transition period finished on the 30 January 2025.

In Q2 2026, an average of 208 new clinical trial applications were submitted per month in CTIS. The median time from submission to decision for new initial clinical trial applications is 109 days[1].

[1] The applications could be affected by the "winter clock stop" and by the Regulation (EEC, EURATOM) No 1182/71 of the Council of June 1971, determining the rules applicable to periods, dates and time limits. (Available at: https://eur-lex.europa.eu/legal). The "winter clock stop" for the Clinical Trials Information System (CTIS) refers to a designated period during the winter holidays when regulatory timelines are paused. This allows regulatory authorities and sponsors to manage workloads effectively during the holiday season, ensuring that deadlines do not coincide with staff leave periods. Due to this winter clock stop, the timelines for the applications may be affected.

A total of 14,458 clinical trial applications have been submitted since the launch of CTIS *(for more details, please refer to the metric "Clinical trials per applicable statuses")*.

At the time when the report is generated, more than 6,725 initial clinical trials are ongoing in EU/EEA under the CTR.

The most commonly investigated therapeutic area is Neoplasms (Tumours).

As part of the monitoring activities of the clinical trial environment, **Key Performance Indicators** (KPIs) have been defined and are measured against targets over the period January 2026 until December 2030.

- The first KPI is about attractiveness, measured by the number of multinational clinical trials authorised in the EU/EEA.

  Before the changes observed with Brexit, COVID-19 and CTIS, the average number of multinational clinical trials authorised per month was 78.

  The aim is to have an additional 500 multinational clinical trials authorised over a 5-year period.

  Meeting the target of 500 **additional** multinational clinical trials in 5 years equates to 100 extra per year, and 25 extra per quarter, giving a new monthly target of 86 trials (78+8). These are indicative figures with fluctuations anticipated over time.

  Measurement of the cumulative number of multinational clinical trials authorised by the end of Q2 2026 revealed that the total exceeded by 34 trials the Q2 target of 50 additional trials year-to-date compared to historical average (i.e. 3,130 trials *vs* target of 3,096 trials), reflected in the following monthly figures:

  - The number of multinational trials authorised in the month of April 2026 was 115
  - The number of multinational trials authorised in the month of May 2026 was 86
  - The number of multinational trials authorised in the month June 2026 was 99

- The second KPI is about faster access to treatment, measured by the percentage of clinical trials recruiting patients at the first clinical investigator site in the EU/EEA within 200 days of the submission of the clinical trials application. This period covers application assessment and authorisation, as well as investigational site contracting, initiation and activation; therefore, it includes a number of steps that fall outside the EU level CTR.

  In Q2 2026, the figures have been consistently around 40% of the total number of clinical trials recruiting within the target timelines:

  - As of 30 April 2026, the percentage of trials recruiting within 200 days was 40.6%
  - As of 31 May 2026, the percentage of trials recruiting within 200 days was 40.7%
  - As of 30 June 2026, the percentage of trials recruiting within 200 days was 40.8%

  Trials conducted by commercial sponsors are closer to meeting the target, while trials conducted by non-commercial sponsors face a longer time between application submission to the start of participant recruitment.

Progress towards both targets will be reviewed annually to ensure they remain ambitious, realistic and aligned with the shared objective of making the EU/EEA a more attractive place to conduct high-quality clinical research.

Contents

Chapter 1

Submitted initial clinical trial applications

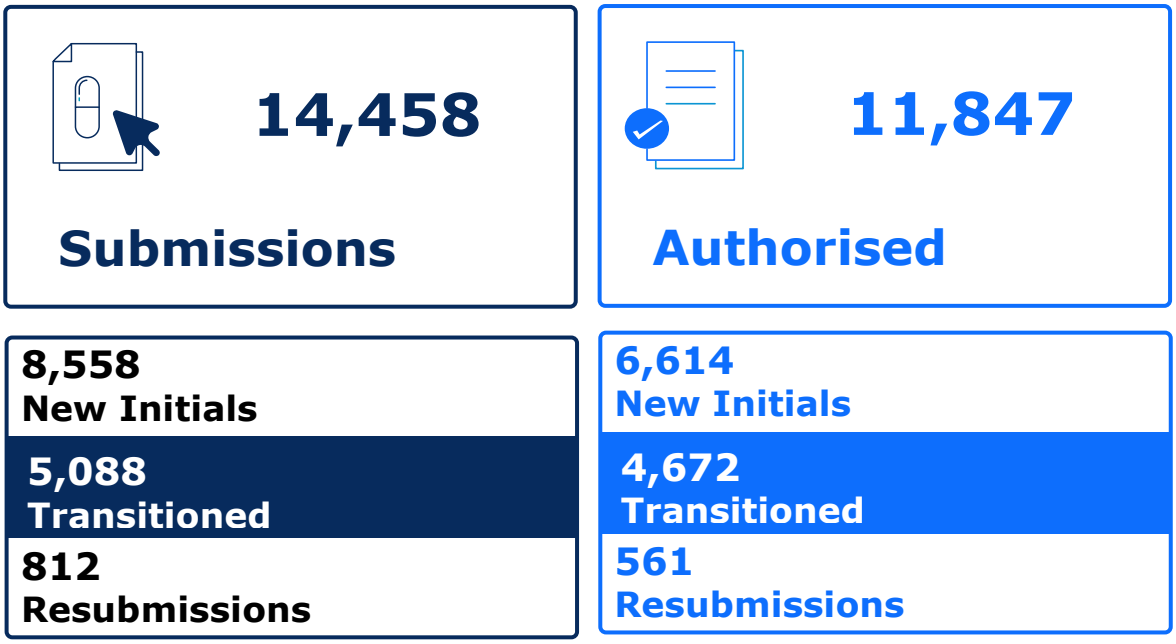
Chapter 1 of this report provides information on **submitted** initial clinical trial applications (CTAs), presented on the applicable statuses.

For detailed information on **authorised** clinical trials please refer to chapter 2 of this report.

Initial clinical trial applications are those applications:

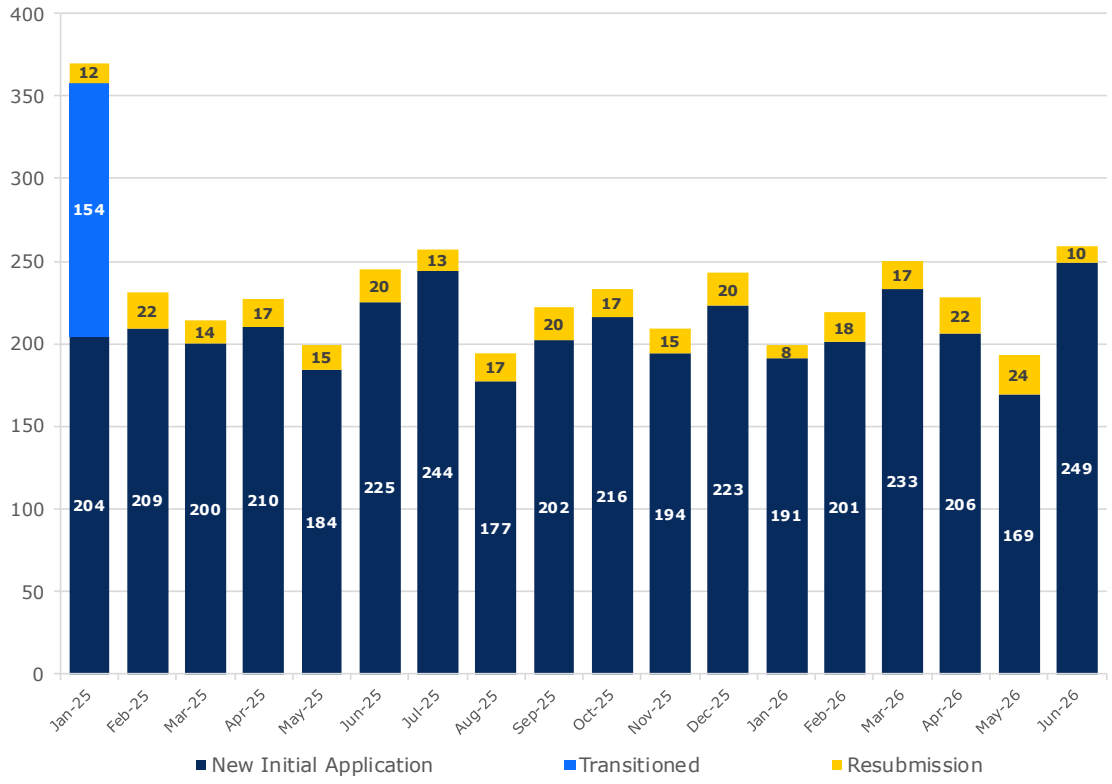
- new initial clinical trial applications submitted in CTIS by the sponsors under the Clinical Trials Regulation (EU) 536/2014 (CTR);
- trials which were already authorised under the regime of Clinical Trials Directive 2001/20/EC (CTD) and that have been transitioned to the regime of CTR;
- resubmitted initial clinical trial applications, which were previously either withdrawn, lapsed, or not authorised.

The overview below presents the **cumulative numbers** for initial clinical trial applications submitted since 31 January 2022 *(for more details, please refer to the metric "Clinical trials per applicable statuses")*.



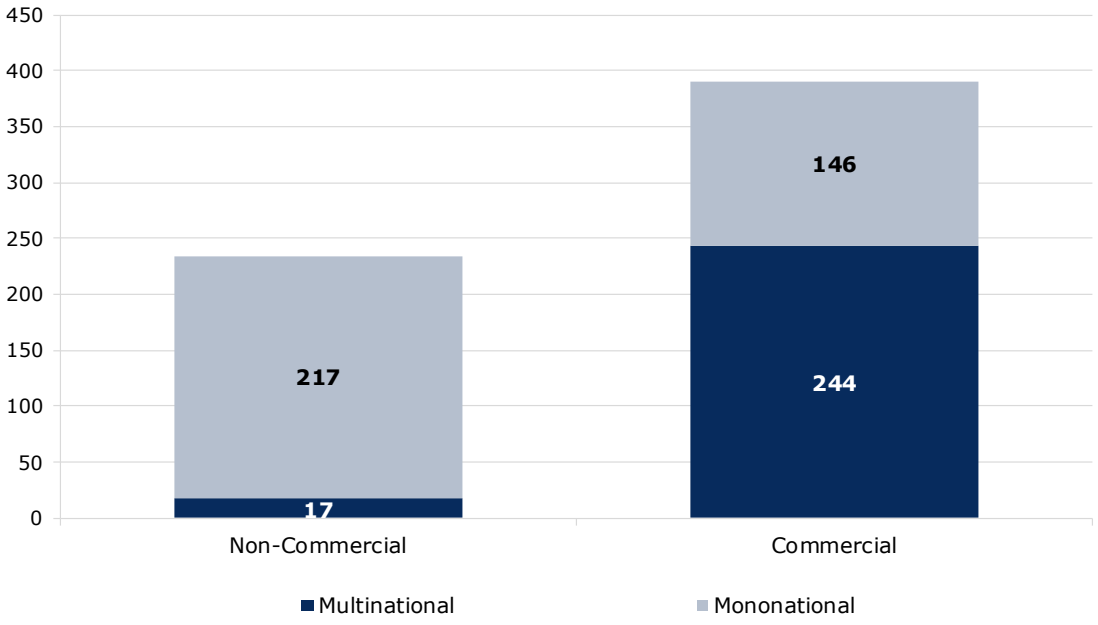
Monthly submissions of initial clinical trial applications

In April-June 2026, 680 initial clinical trial applications have been submitted, of which 624 new initial CTA and 56 are resubmissions of previously submitted initial applications. According to Article 98 of the Clinical Trials Regulation (EU) 536/2014, the transition period finished the 30 January 2025. The graph below shows the data for the last 18 months.



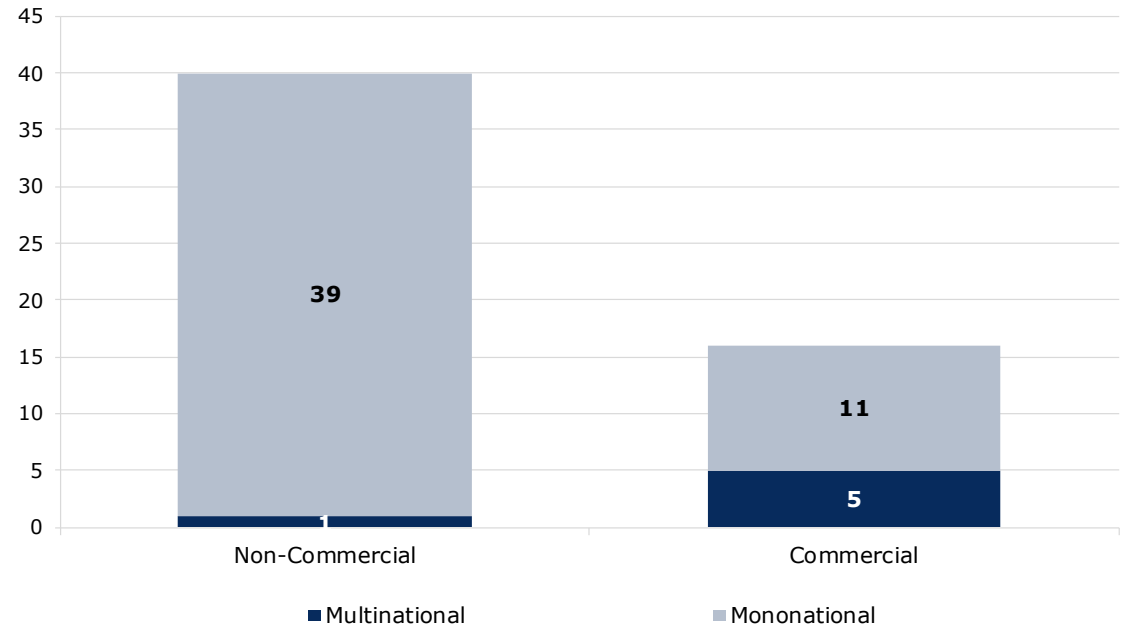
New initial clinical trial applications per sponsor type and mono- vs multinational trials

The graph below shows the split of submissions of new initial clinical trial applications in April-June 2026 into commercial/non-commercial sponsors and mononational versus multinational trials.



Resubmitted initial clinical trial applications per sponsor type and mono- vs multinational trials

The graph below shows the split of resubmitted initial clinical trial applications in April-June 2026 into commercial/non-commercial sponsors and mononational versus multinational trials.



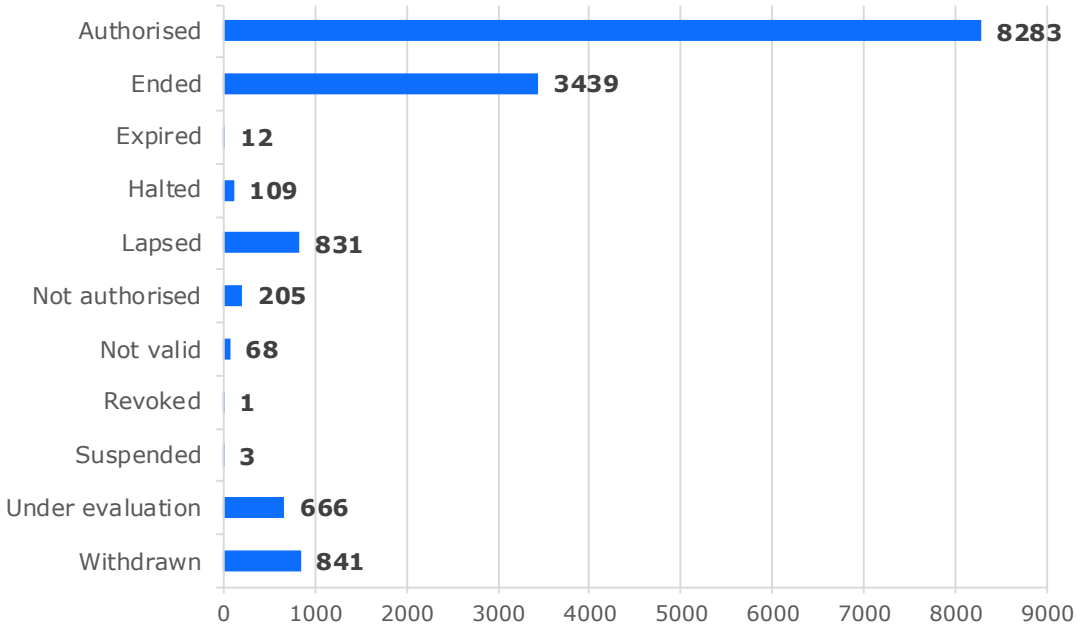
Clinical trials per applicable statuses

Since 31 January 2022, a total of 14,458 initial clinical trial applications have been submitted in CTIS.

The graph below shows the number of trials submitted since 31 January 2022 per applicable overall status at EU level. It should be noted that the status 'authorised with conditions' does not appear in the graph below as it is a status applicable **at the level of the Member States Concerned**.

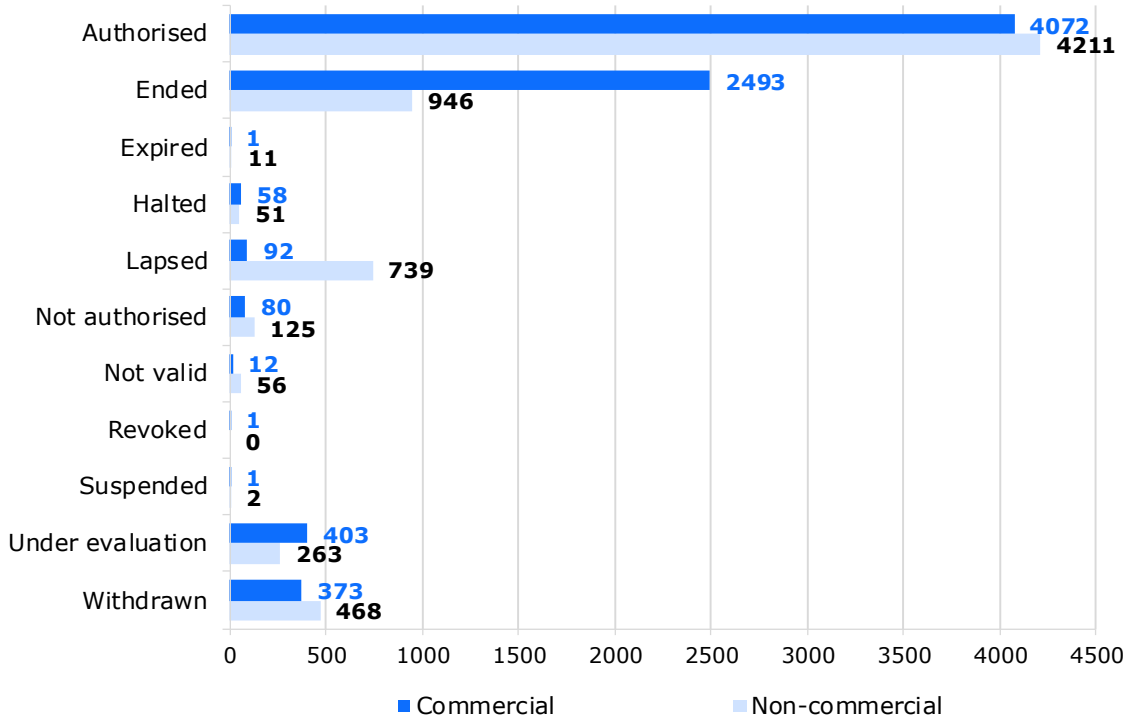
Clinical trials per applicable statuses

The graph below shows the status of each clinical trial as recorded in CTIS at the time when the report is generated.



Clinical trials classified per statuses and per sponsor type

The graph below shows the cumulative figure per status of each clinical trial as recorded in CTIS at the time when the report is generated, in combination with information on sponsor type.



Distribution of submitted new initial clinical trial applications per Member State Concerned

The overview below provides information on new initial clinical trial applications – full applications (Part I and Part II) or Part I only – submitted since 31 January 2022 by looking at Member States involvement in mono/multinational trials, as Reporting Member State (RMS)[2] and Member State Concerned (MSC). It is important to contextualise the number reported in the table vis-à-vis the Member States population [Statistics | Eurostat (europa.eu)].

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

Member State	Multinational Trials		Mononational Trials	Total number of Initial CTAs
	MSC	*Of which as RMS*		
Austria	602	93	83	685
Belgium	1182	211	357	1539
Bulgaria	640	23	48	688
Croatia	185	0	1	186
Cyprus	8	0	1	9
Czechia	935	145	106	1041
Denmark	695	234	355	1050
Estonia	98	13	10	108
Finland	252	77	75	327
France	2145	294	864	3009
Germany	2210	801	592	2802
Greece	625	6	40	665
Hungary	834	47	44	878
Iceland	13	0	2	15
Ireland	235	24	27	262
Italy	2063	265	340	2403
Latvia	116	10	9	125
Lithuania	134	15	4	138
Luxembourg	4	0	1	5
Netherlands	1087	209	630	1717
Norway	284	49	93	377
Poland	1767	200	144	1911
Portugal	470	52	103	573
Romania	565	16	70	635
Slovakia	322	27	6	328
Slovenia	45	4	5	50
Spain	2701	737	685	3386
Sweden	507	116	186	693

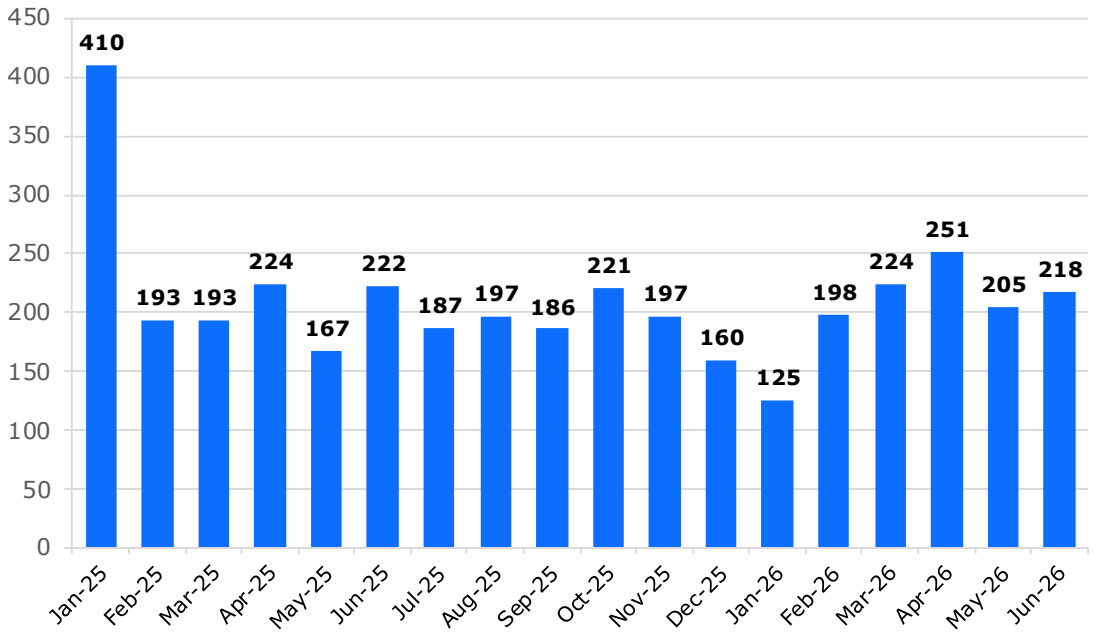
Chapter 2

Authorised clinical trials

Since 31 January 2022, a total of 12,052 have received a decision in CTIS, of which 11,847 received a positive decision authorising the clinical trial. The graph below includes figures on both authorised and not authorised clinical trials in the last 18 months.

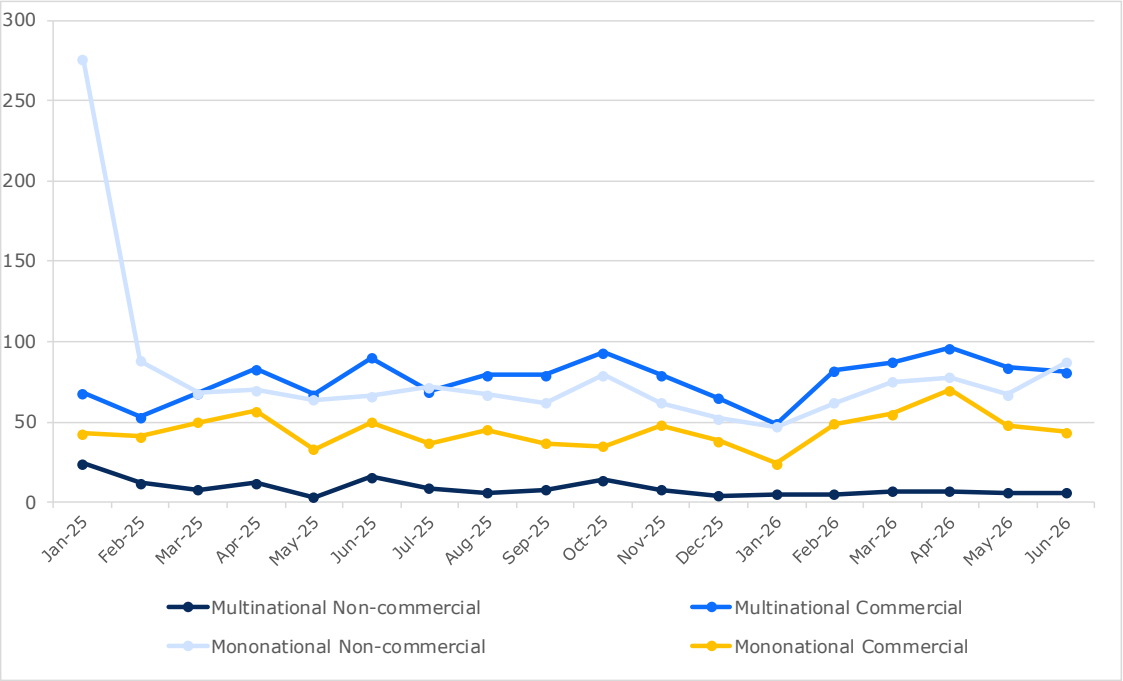
In April-June 2026, of the 674 initial clinical trial with a decision, 662 have been authorised.

The high number of decisions in January 2025 is due to the higher number of transitioning applications that were submitted before the end of the transitional period.



Mono- vs multinational trial, for which a decision has been issued, and in relation to the sponsor type

The graph below shows the number of trials for which, in the last 18 months, a decision has been issued in CTIS. The graph below includes figures on both authorised and not authorised clinical trials as well as commercial/non-commercial sponsor.

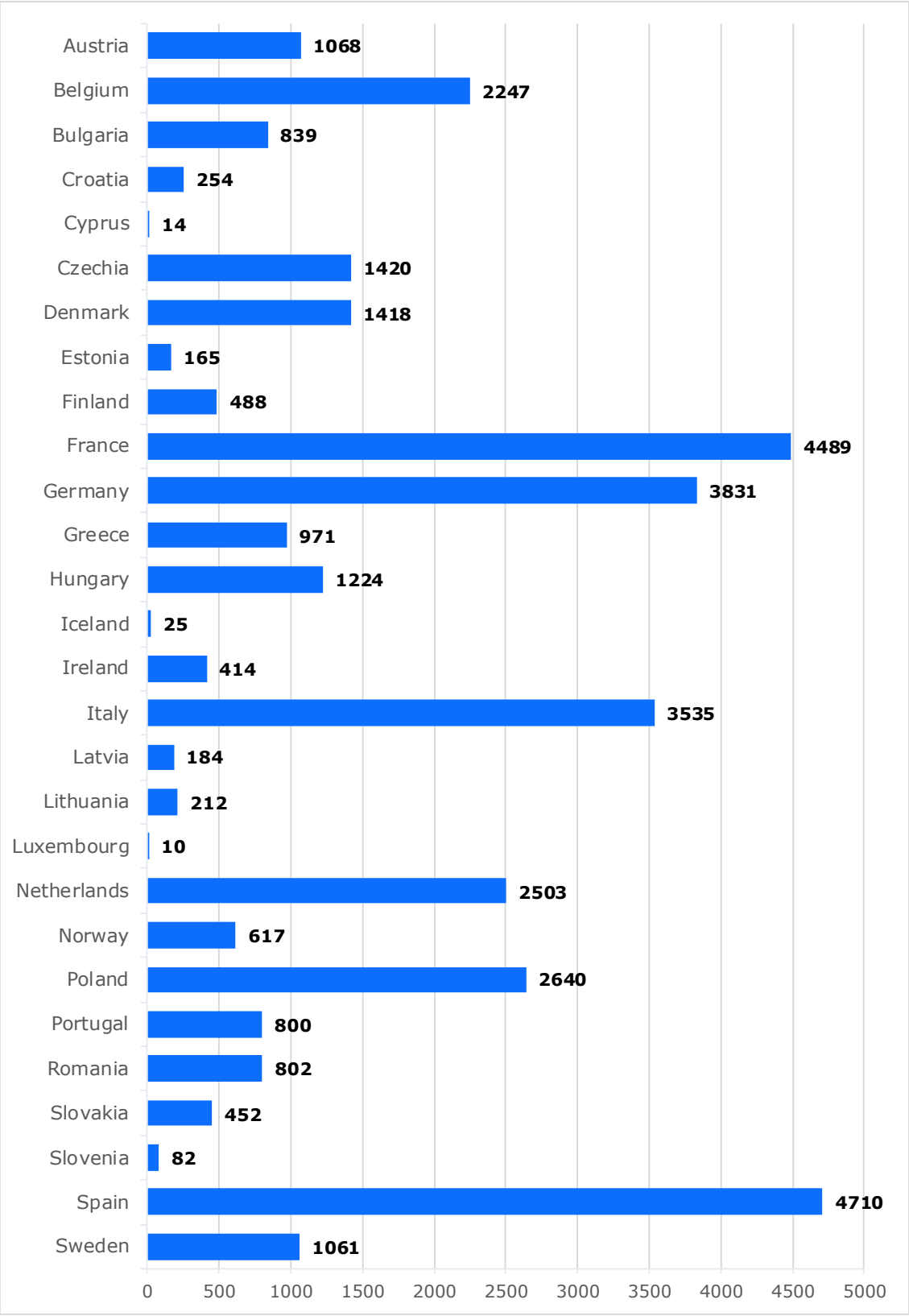


As of 30 June 2026, 5,415 multinational clinical trials have a decision in CTIS, with an average number of 6 Member States Concerned per trial.

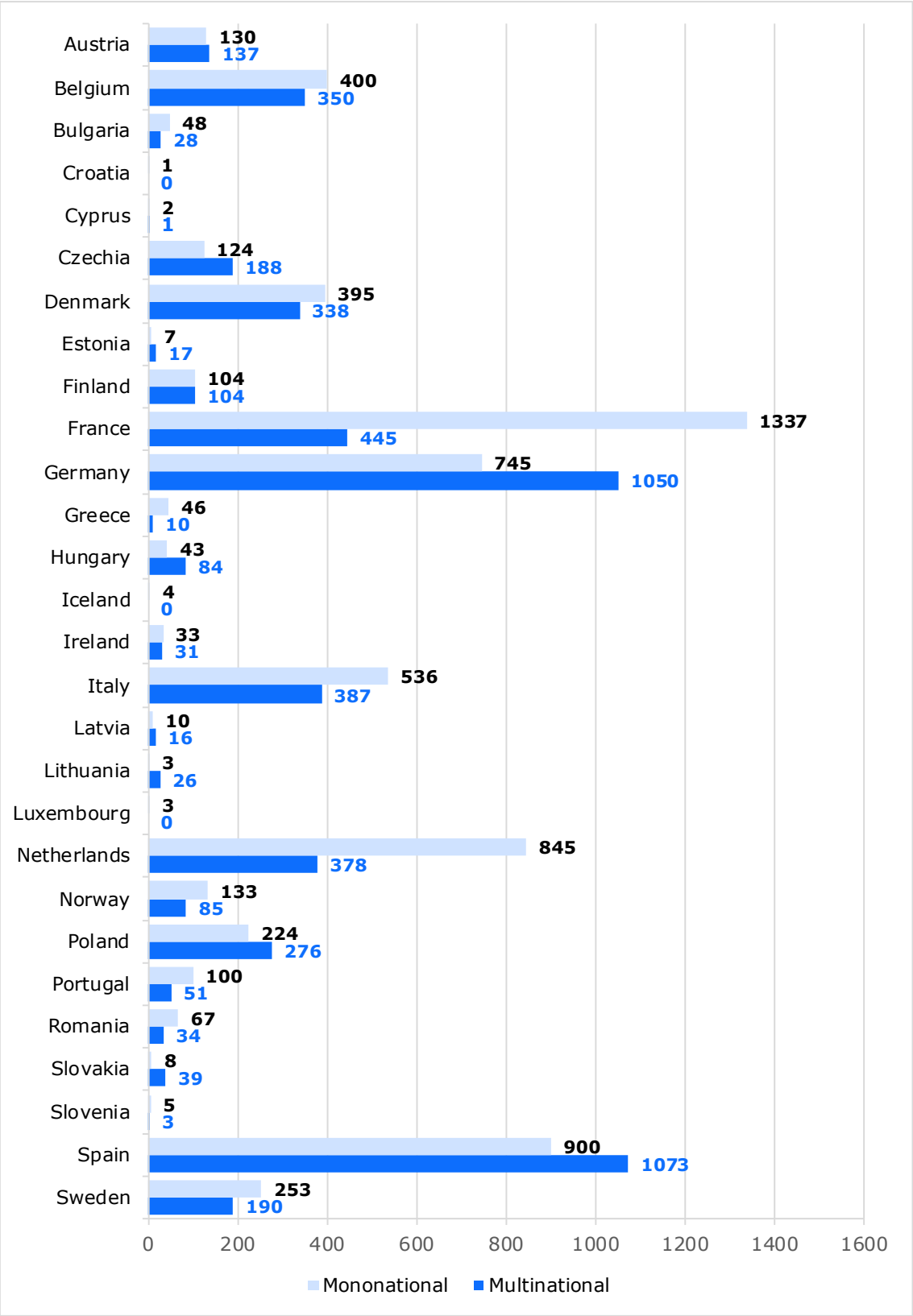
Distribution of **authorised** clinical trials per Member State Concerned and appointment of Reporting Member State

The graph below shows the number of clinical trials authorised since 31 January 2022. The figures indicate how many times a Member State has been involved as Member State Concerned[3] in an initial clinical trial application even if it has not authorised yet the trial in its country.

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



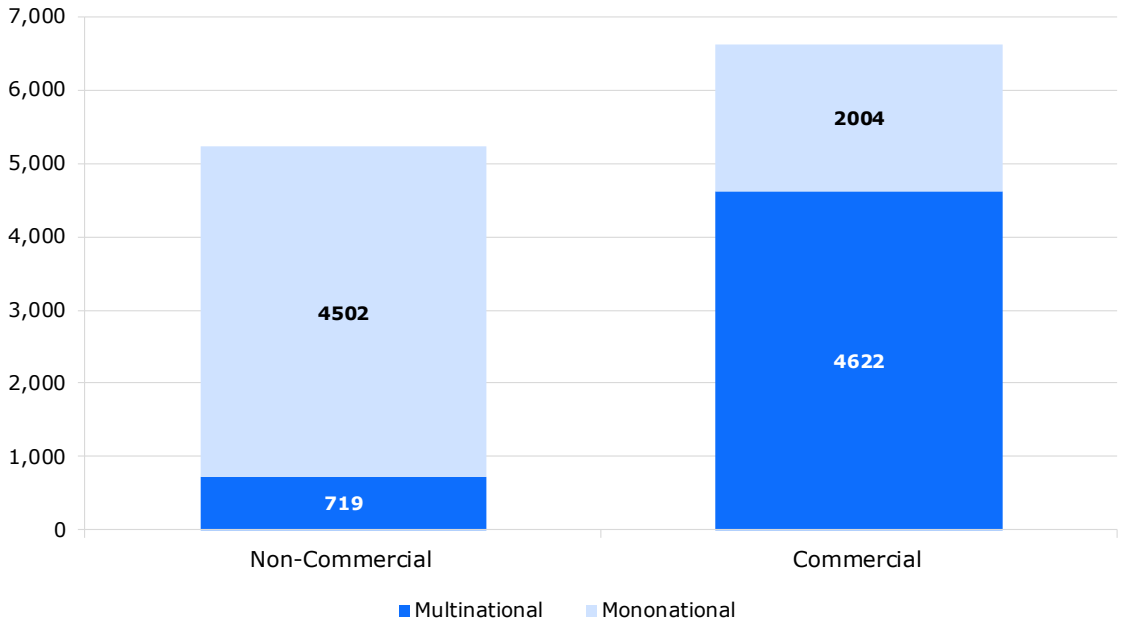
The graph below shows the distribution of appointment of Reporting Member State (RMS), amongst the applicable Member States Concerned, in authorised mono- and multinational trials.


Austria 130 137
Belgium 400 350
Bulgaria 48 28
Croatia 1 0
Cyprus 2 1
Czechia 124 188
Denmark 395 338
Estonia 7 17
Finland 104 104
France 1337 445
Germany 745 1050
Greece 46 10
Hungary 43 84
Iceland 4 0
Ireland 33 31
Italy 536 387
Latvia 10 16
Lithuania 3 26
Luxembourg 3 0
Netherlands 845 378
Norway 133 85
Poland 224 276
Portugal 100 51
Romania 67 34
Slovakia 8 39
Slovenia 5 3
Spain 900 1073
Sweden 253 190
0 200 400 600 800 1000 1200 1400 1600
Mononational
Multinational

Authorised clinical trials, with information whether the trial is a mono- vs multinational and in relation to sponsor type

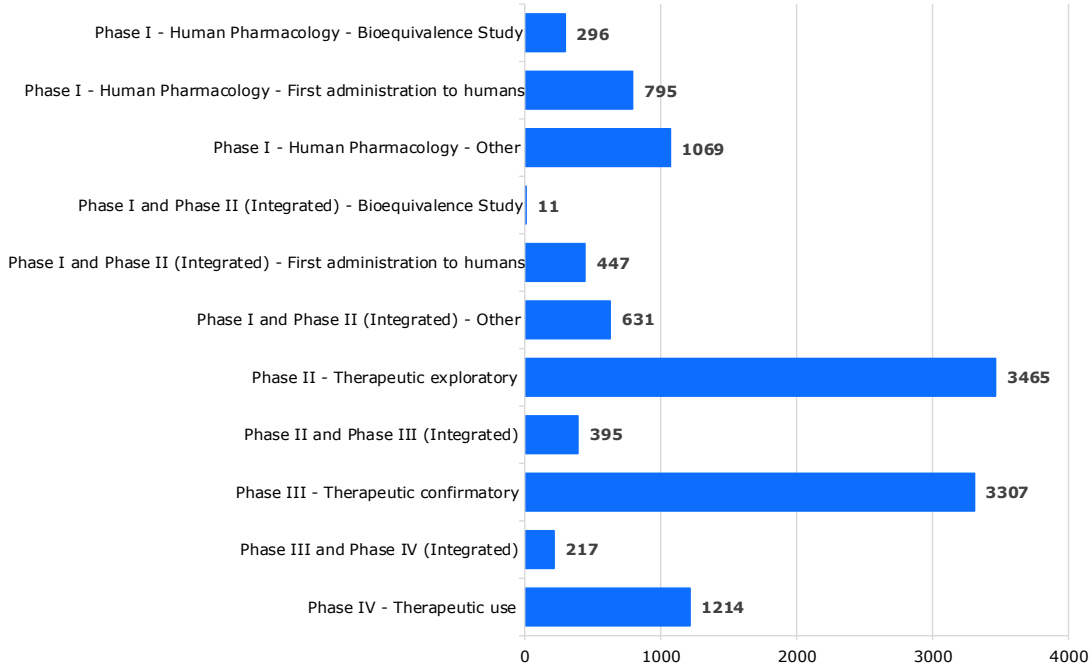
The graph below shows the number of clinical trials authorised since 31 January 2022, split into mononational/multinational and per sponsor type.

The graph shows a majority of authorised mononational clinical trials conducted by non-commercial sponsors. On the contrary the majority of authorised clinical trials conducted by commercial sponsors are multinational.



Authorised clinical trials per phase (i.e. I, II, III, IV, as well as first in human clinical trials or combined phases)

The graph below shows the number of clinical trials authorised since 31 January 2022, broken down per trial phase.



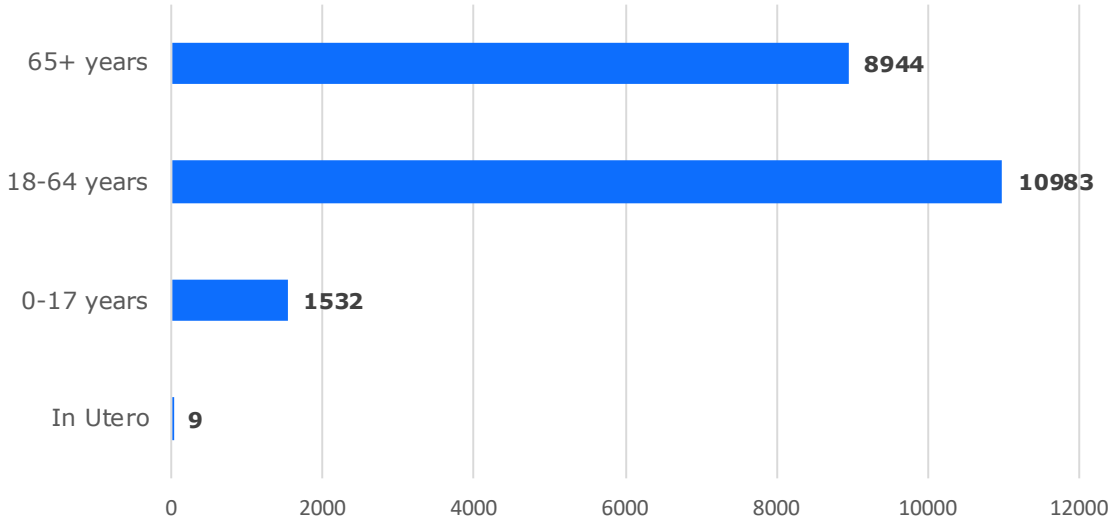
Clinical trials per population type and rare disease

As of 30 June 2026, 6,726 clinical trials were reported as ongoing in CTIS. 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 sites[4].

The graph below illustrates some features of the groups and subgroups of participants involved in clinical trials that have been authorised in the EU/EEA.

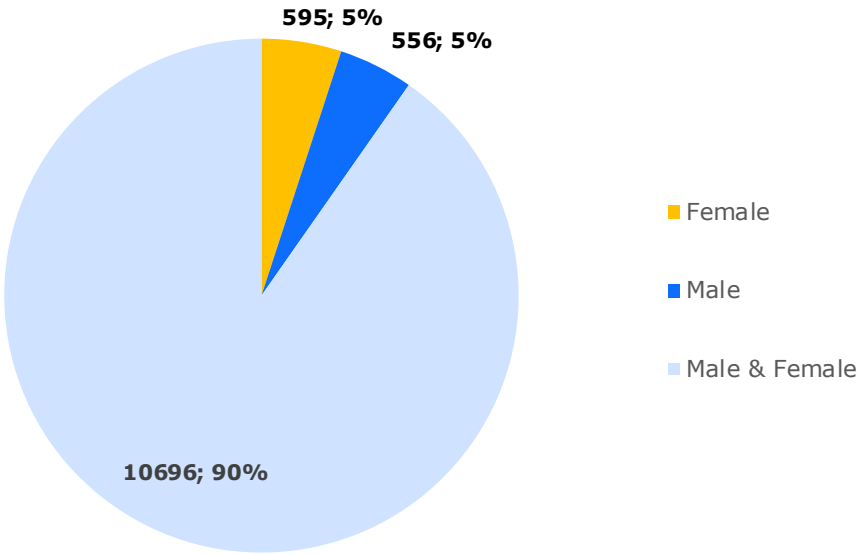
[4] Details on recruitment status are based on the information reported by the trial sponsor in CTIS.

By Age of clinical trials participants

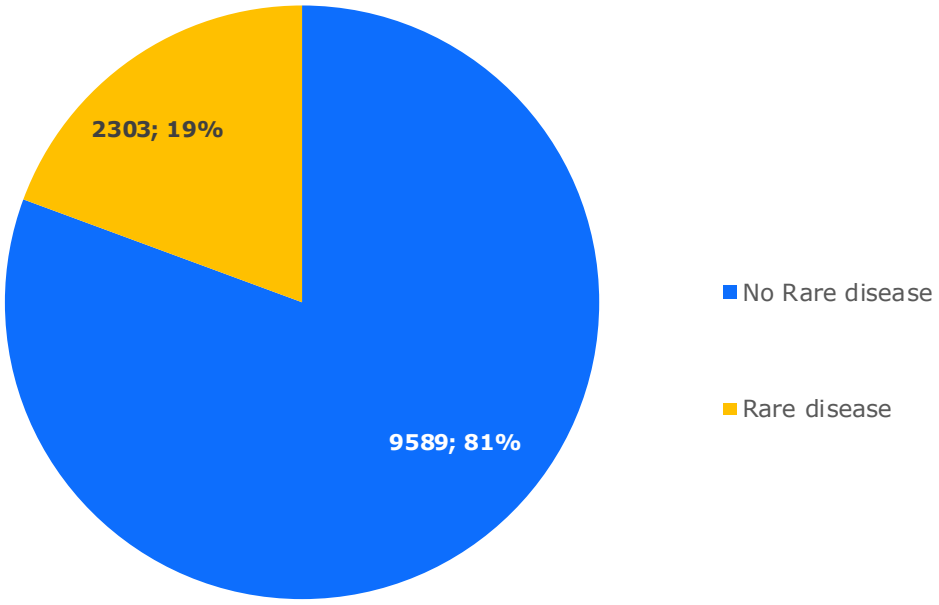


It is important to note that various age categories may be addressed in one clinical trial (e.g. a clinical trial may be for age "+65" as well as for age "18-64" and in this case it would be counted twice). Therefore, the reader should not sum the number of clinical trials for each age category and consider the total as the total of clinical trials.

By Gender of clinical trials participants



Clinical trials with rare disease participants

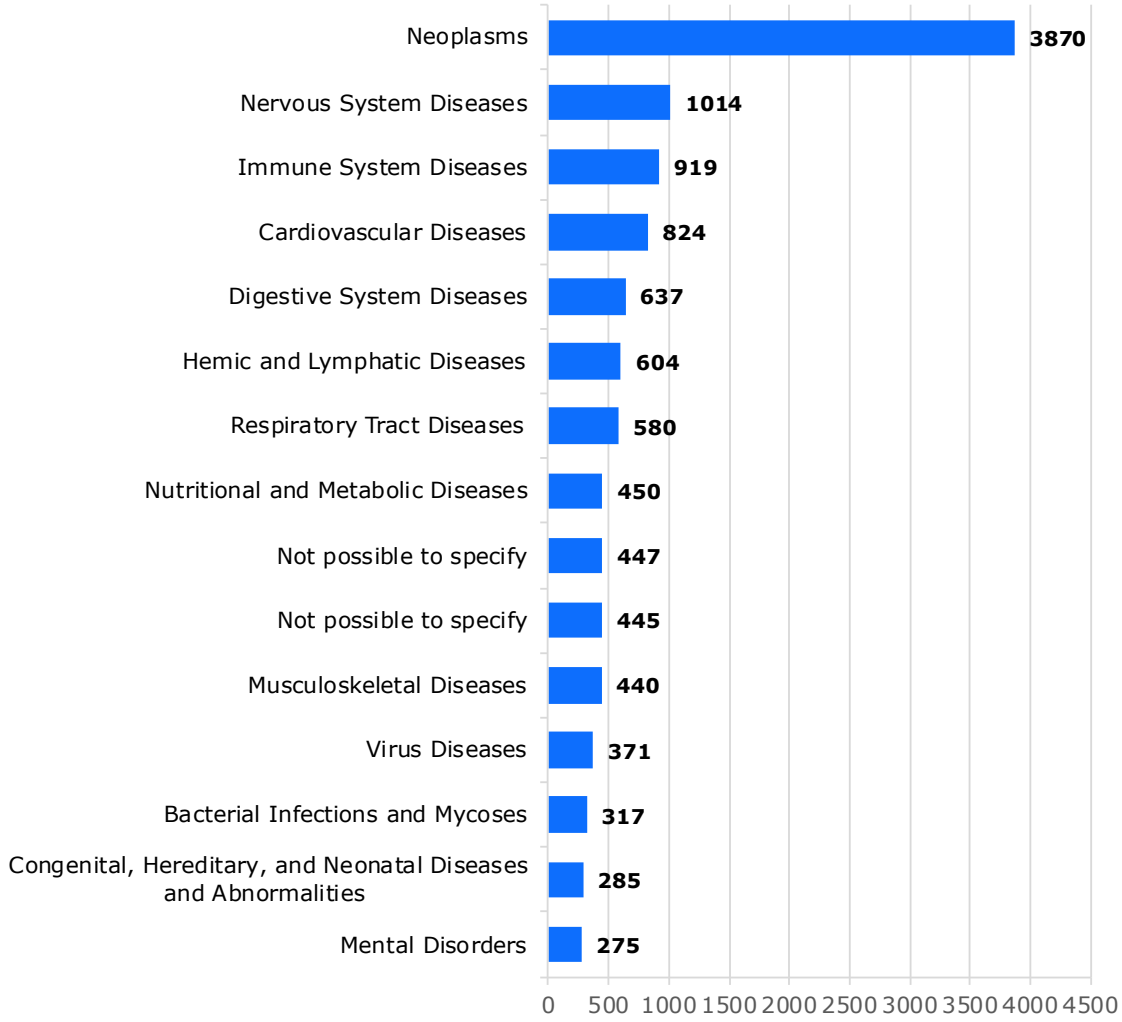


It is important to note that more than one disease could be investigated in one clinical trial (e.g., a clinical trial may be for a rare disease as well as for a non-rare disease and in this case it would be counted twice). Therefore, the reader should not sum the number of clinical trials for Rare disease/No Rare disease and consider the total as the total of clinical trials.

Authorised clinical trials per therapeutic area

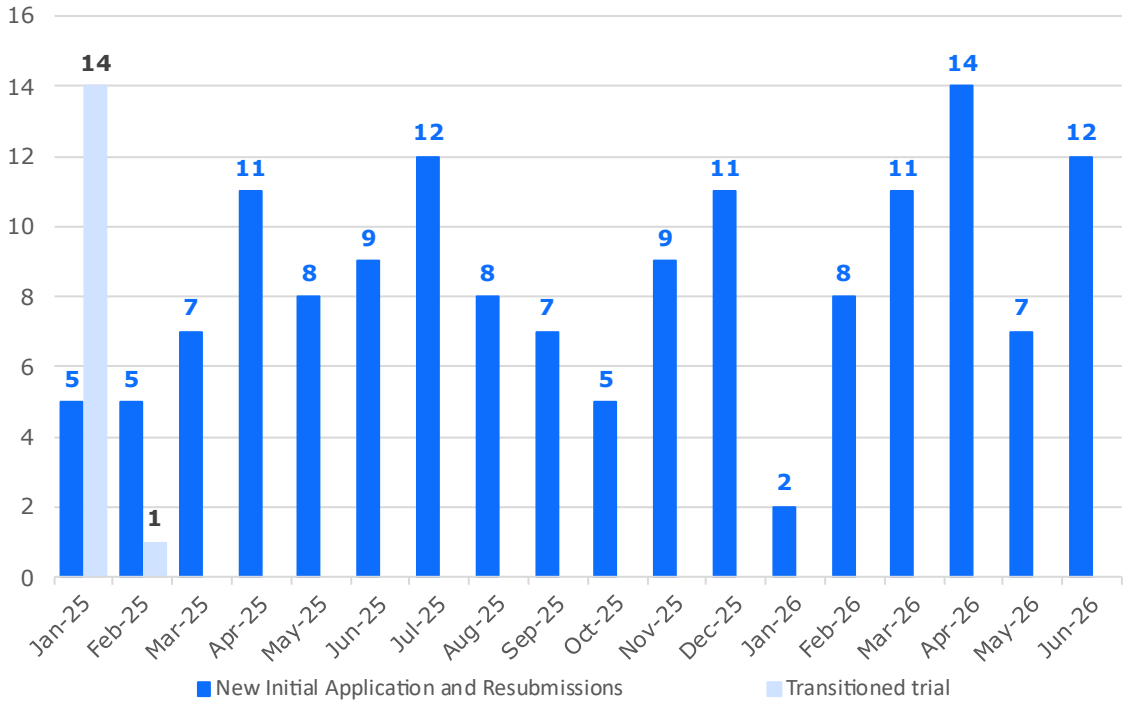
The graph below shows the number of clinical trials authorised since January 2022, broken down per therapeutic area[5], showing the most frequent 15 therapeutic areas.

[5] In case a clinical trial investigates several therapeutic areas, it is counted in each of such identified therapeutic areas.



Authorised clinical trials with an ATMP

In April-June 2026, 33 clinical trials with an Advanced Therapy Medicinal Product (ATMP) have been authorised, bringing the total of authorised clinical trials with ATMPs to 519, as illustrated in the graph below which shows the data for the last 18 months.


16
14
12
10
8
6
4
2
0
5
14
5
1
7
11
8
9
12
8
7
5
9
11
2
8
11
14
7
12
Jan-25
Feb-25
Mar-25
Apr-25
May-25
Jun-25
Jul-25
Aug-25
Sep-25
Oct-25
Nov-25
Dec-25
Jan-26
Feb-26
Mar-26
Apr-26
May-26
Jun-26
New Initial Application and Resubmissions
Transitioned trial

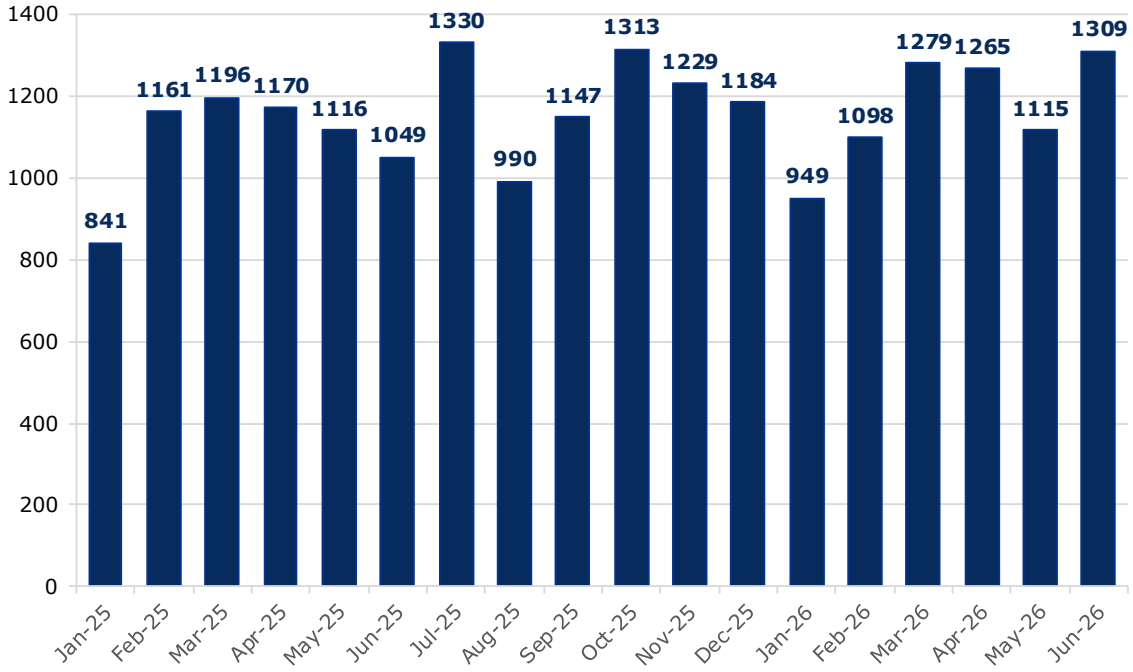
Chapter 3

Substantial modification applications

Substantial modifications[6] are those modifications that have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial.

Submitted substantial modification applications

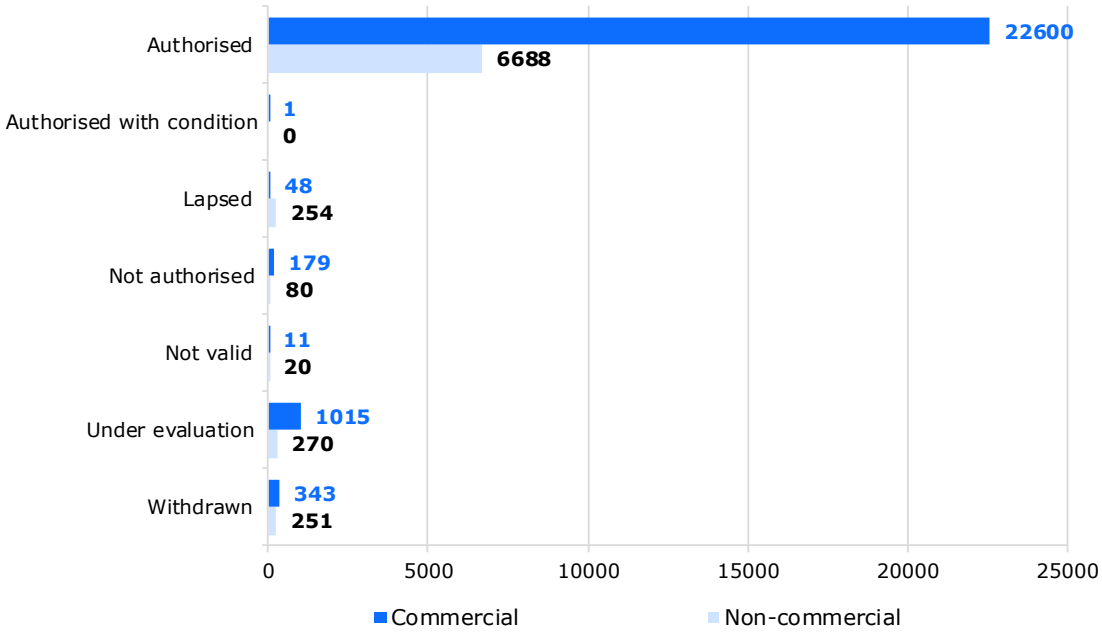
Overall, 31,760 distinct substantial modification applications, affecting 8,519 trials, have been submitted since the launch of the system on 31 January 2022, of which 3,689 substantial modifications submitted in April-June 2026, affecting 2,734 trials. The graph below shows the data for the last 18 months.



Substantial modification applications per applicable statuses and by sponsor type

Since 31 January 2022, 31,760 distinct applications for substantial modifications were submitted in CTIS, presented below per application status and sponsor type.

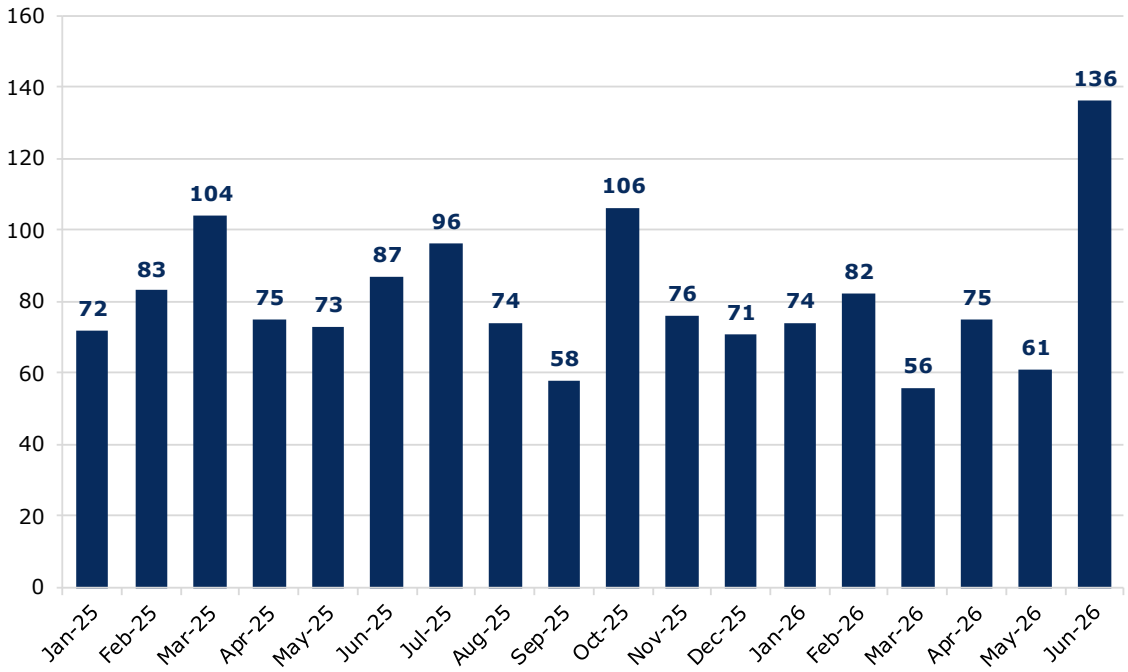
[6] Substantial modifications for Part I only, or Part II only or Part I and Part II, are foreseen in Chapter II of the Clinical Trials Regulation (EU) No 536/2014.


Authorised
22600
6688
Authorised with condition
1
0
Lapsed
48
254
Not authorised
179
80
Not valid
11
20
Under evaluation
1015
270
Withdrawn
343
251
0
5000
10000
15000
20000
25000
Commercial
Non-commercial

Chapter 4
Addition of a Member State Concerned

Submitted addition of Member States Concerned applications

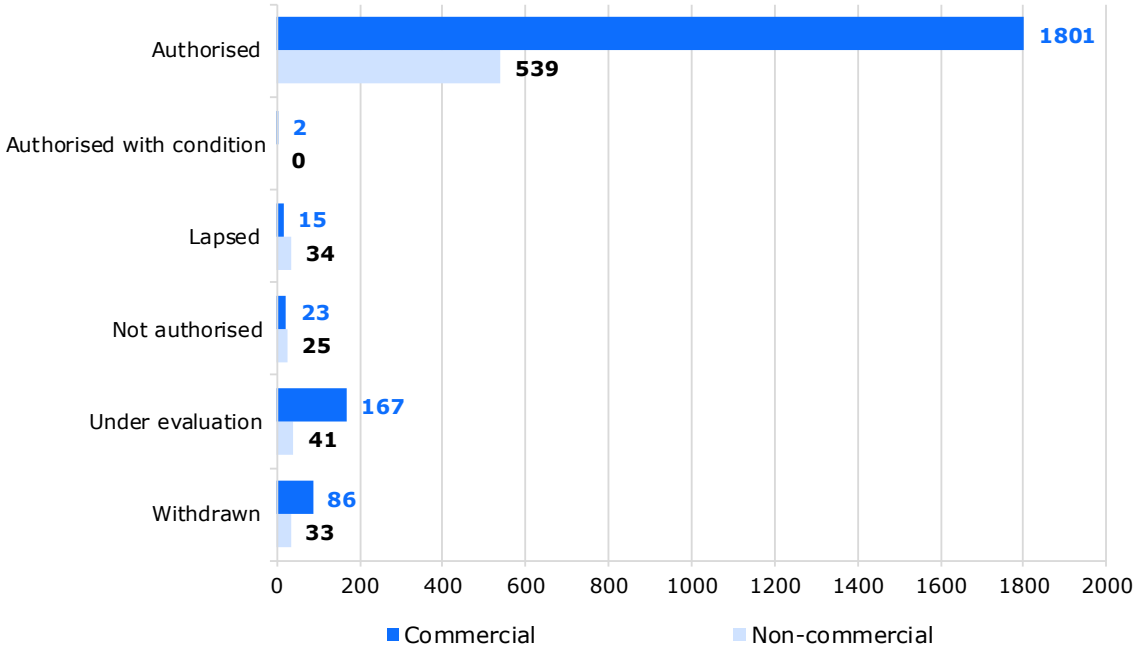
Since 31 January 2022, 2,766 distinct applications for the addition of a new MSC[7], affecting 1,063 trials, have been submitted in CTIS, of which 272 applications for the addition of a new MSC were submitted in April-June 2026, affecting 126 trials. The graph below shows the data for the last 18 months.



Addition of Member States Concerned applications per applicable statuses by sponsor type

Since 31 January 2022, 2,766 distinct applications for the addition of a new MSC have been submitted in CTIS, presented below per application status and sponsor type.

[7] Applications to add a new Member States Concerned are submitted in accordance with the requirements of Article 14 of Regulation (EU) No 536/2014


Authorised
1801
539
Authorised with condition
2
0
Lapsed
15
34
Not authorised
23
25
Under evaluation
167
41
Withdrawn
86
33
0
200
400
600
800
1000
1200
1400
1600
1800
2000
Commercial
Non-commercial

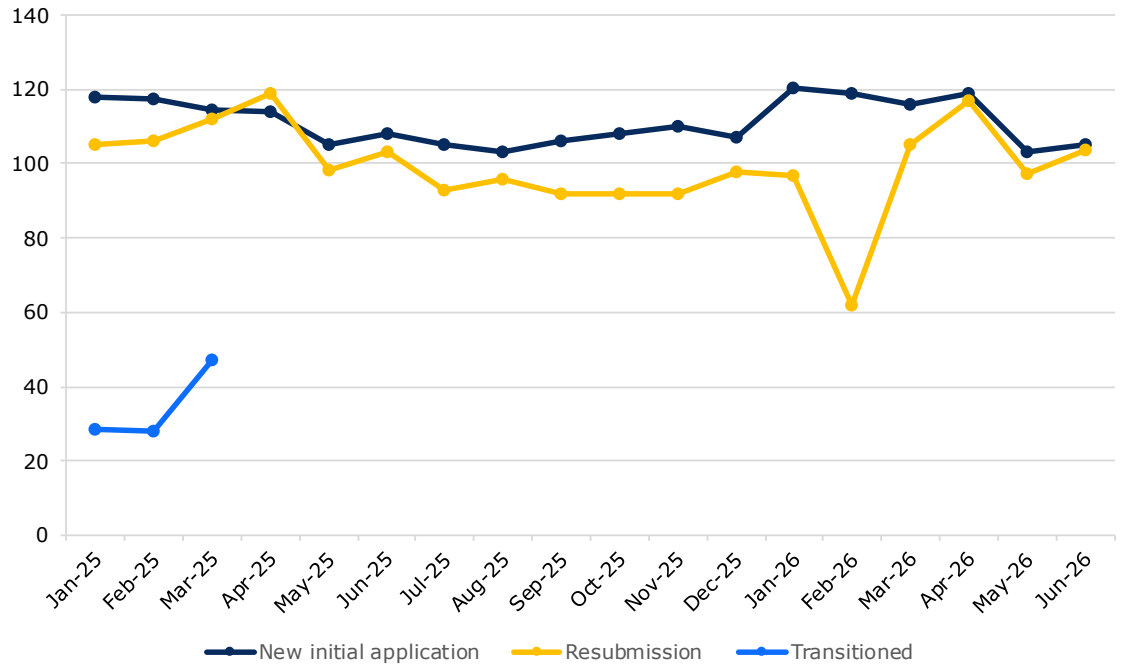
Chapter 5
Timelines

The graphs below show median timelines, for the last 18 months, from the submission of initial clinical trial applications to different points in time[8].

Median time from submission of initial clinical trial applications to decision

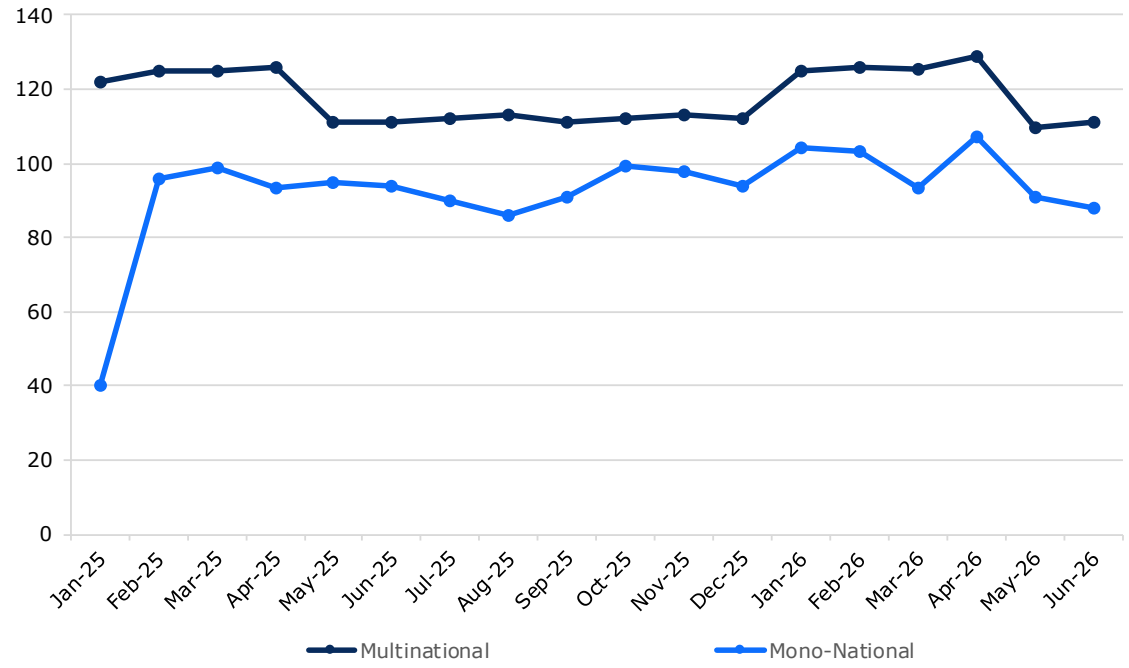
This graph takes into consideration the median number of days between the submission date and the decision date for clinical trials for which the decision has been issued in that particular month. For partial Part I only initial applications, the time requested to issue a decision is calculated from the date sponsors decide to submit the Part II documents.

Median time per new initial application/resubmission and transitional trials from submission of initial clinical trial applications to decision

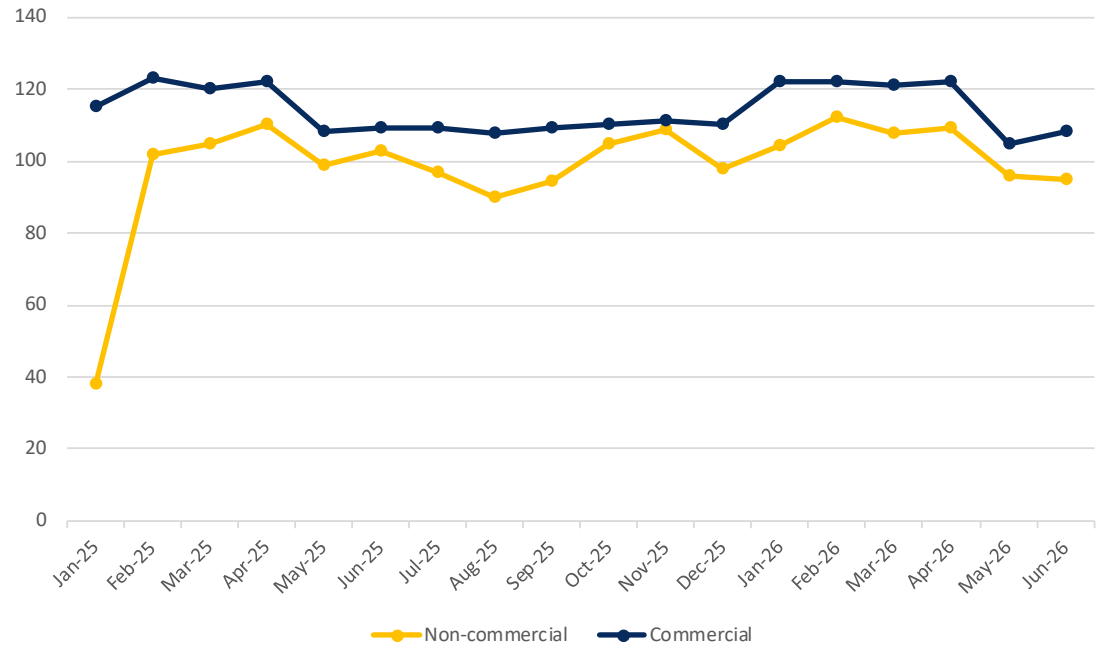


[8] The applications could be affected by the "winter clock stop" and by the Regulation (EEC, EURATOM) No 1182/71 of the Council of June 1971, determining the rules applicable to periods, dates and time limits. (Available at: https://eur-lex.europa.eu/legal). The "winter clock stop" for the Clinical Trials Information System (CTIS) refers to a designated period during the winter holidays when regulatory timelines are paused. This allows regulatory authorities and sponsors to manage workloads effectively during the holiday season, ensuring that deadlines do not coincide with staff leave periods. Due to this winter clock stop, the timelines for the applications may be affected.

Median time per mono- vs multinational clinical trials from submission of initial clinical trial applications to decision



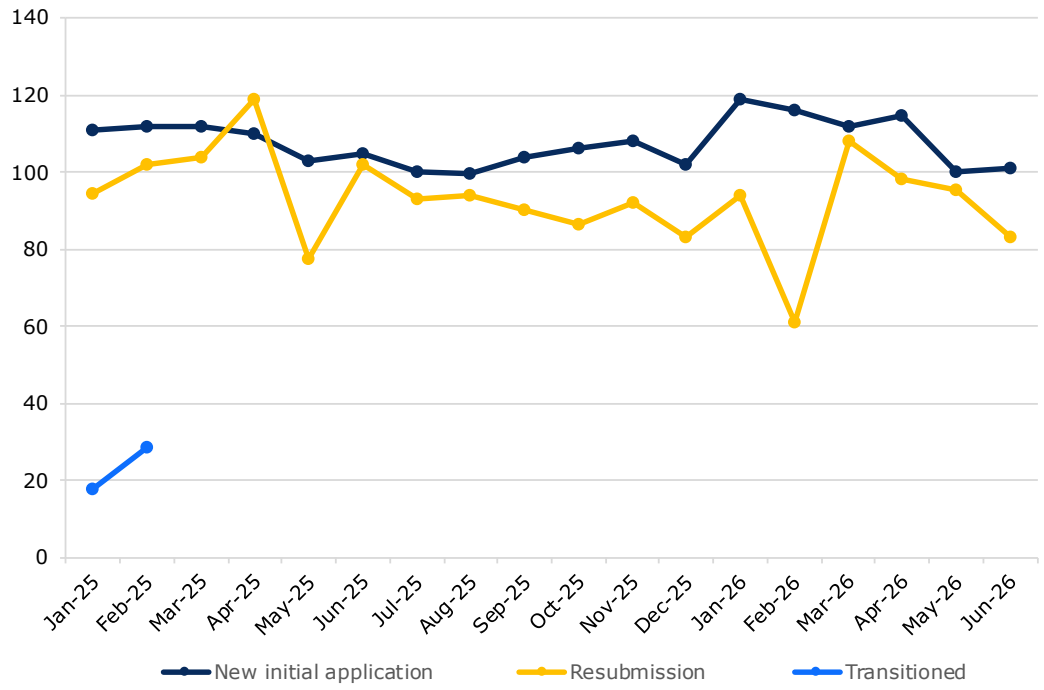
Median time per commercial/non-commercial sponsors from submission of initial clinical trial applications to decision



The shorter timelines observed in the previous graphs for January 2025 are attributable to the expedited review process for transitional trial applications.

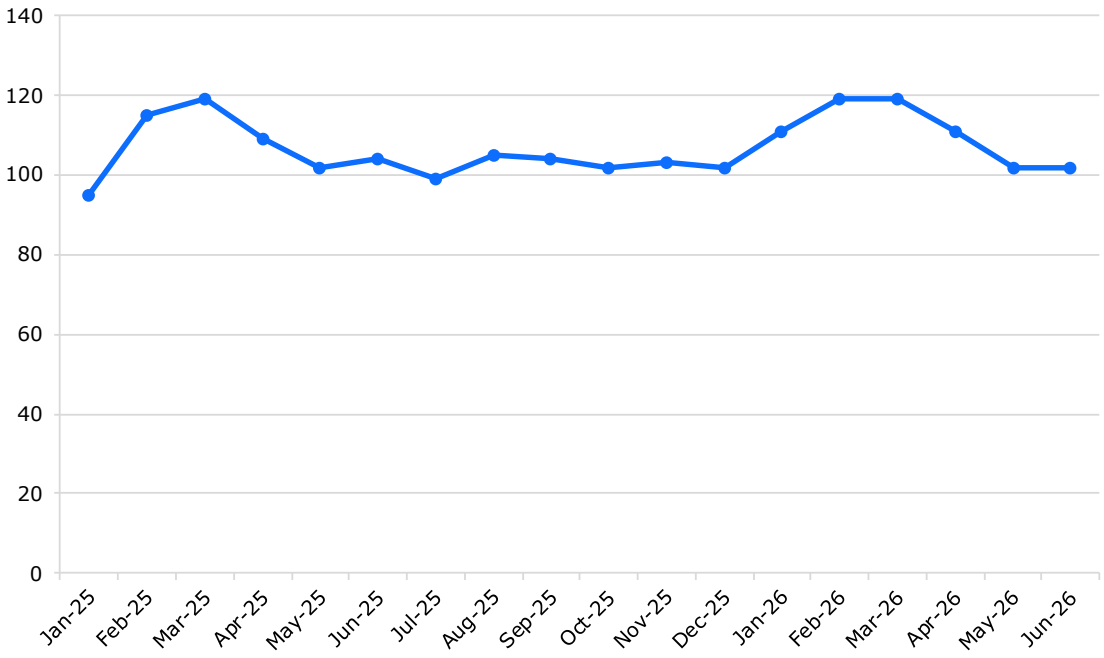
Median time from submission of initial clinical trial applications to Part I conclusion

This graph takes into consideration the median number of days between the submission date and Part I conclusion date for clinical trials for which the Part I conclusion has been issued in that particular month.



Median time from submission of initial clinical trial applications to Part II conclusions

This graph takes into consideration the median number of days between the submission date for Part I (regardless of whether the application was a full Part I and Part II application or a partial Part I only application) and the Part II conclusion date, for each MSC, for clinical trials for which the Part II conclusion has been issued in that particular month. The time requested to reach the Part II conclusion depends on: (i) when the conclusion on Part I is issued, (ii) when sponsors submit Part II documents and (iii) the time to assess Part II documents and issue the Part II conclusion. As per Article 11 of the Clinical Trials Regulation (EU) 536/2014, sponsors are allowed to submit Part II documents at a later date than Part I documents, but within 2 years after the notification of the conclusion on the aspects covered by the assessment of Part I.


140
120
100
80
60
40
20
0
Jan-25
Feb-25
Mar-25
Apr-25
May-25
Jun-25
Jul-25
Aug-25
Sep-25
Oct-25
Nov-25
Dec-25
Jan-26
Feb-26
Mar-26
Apr-26
May-26
Jun-26

Chapter 6
Features of the substances

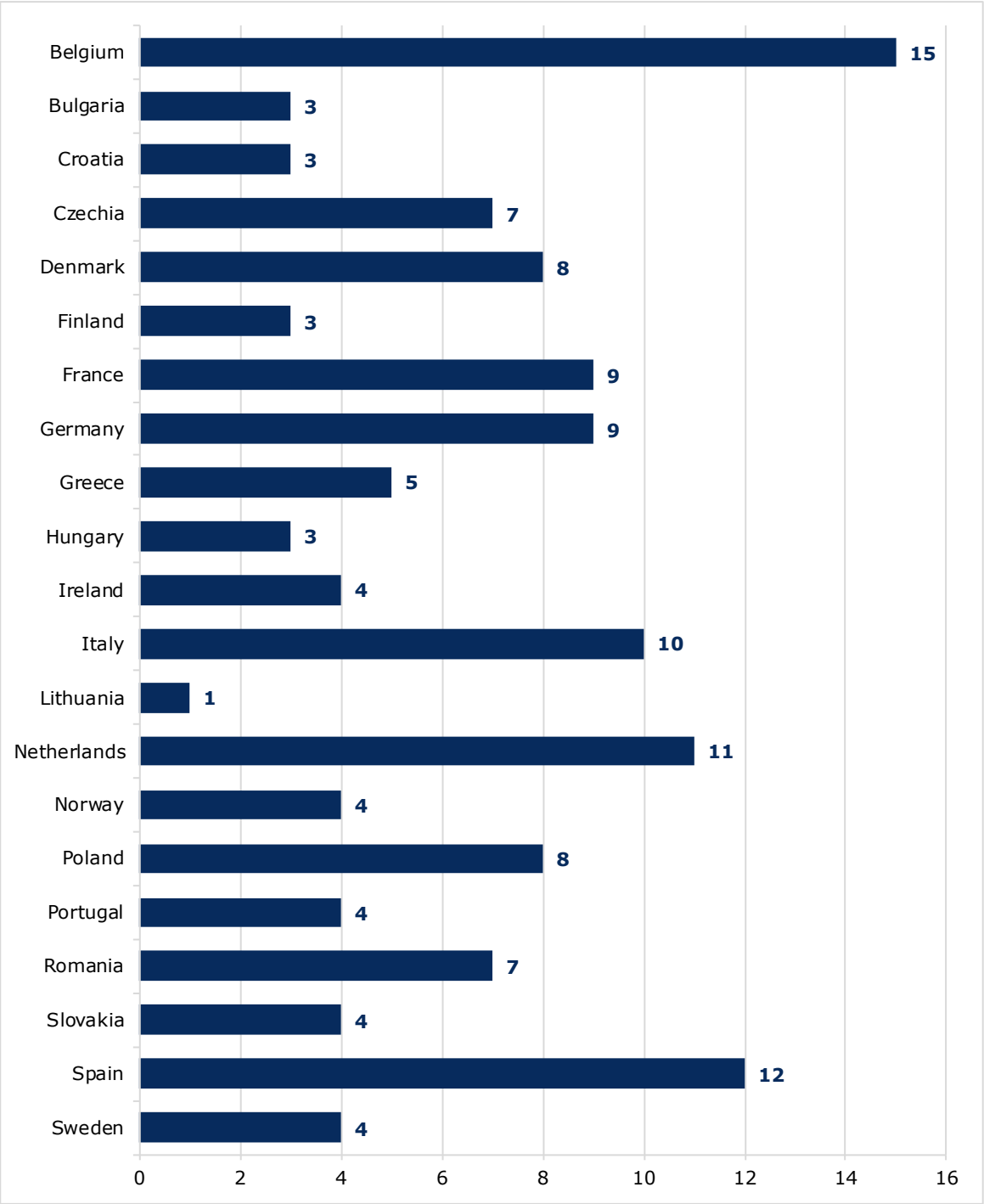
Safety assessing Member States (saMS) appointment

In multinational clinical trials, a safety assessing Member State (saMS) is selected and becomes responsible for the assessment of the safety report and relevant safety information of active substances used in clinical trials, as described in Article(3) of Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials.

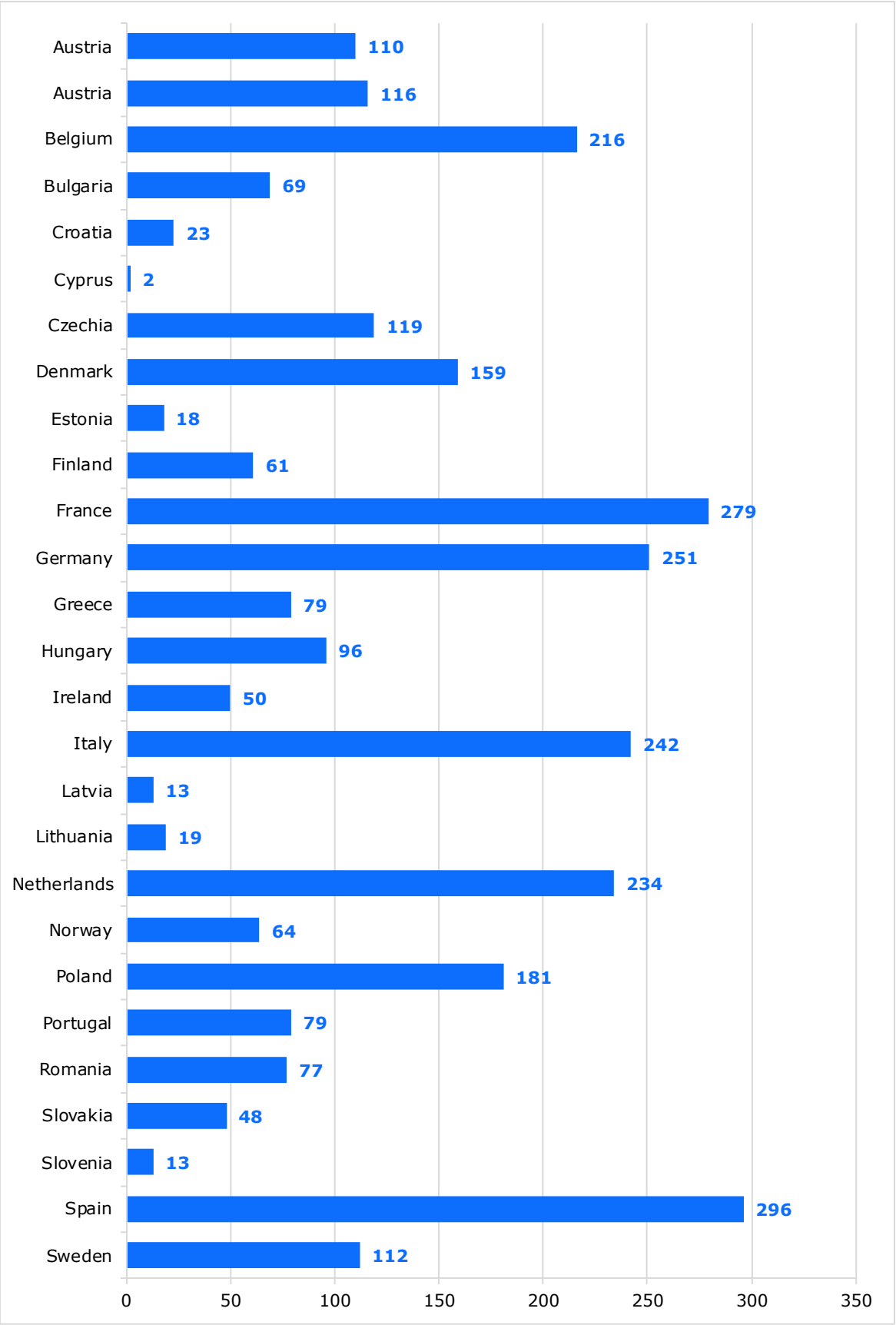
In a mononational clinical trial, the Member State is responsible for the assessment of information related to safety of the active substance. These metrics are not included in the present report. Of note, the Implementing Regulation does not apply to mononational active substances, to active substances in investigational medicinal products used as reference products, including as placebo, or to active substances used in auxiliary medicinal products.

In April-June 2026, Member States authorised application dossiers involving 190 new active substances.

The graph below illustrates how many times between April-June 2026 each Member State has been appointed as safety assessing Member State for an active substance used in multinational clinical trials.



The graph below illustrates the cumulative figures on how many times each Member State has been appointed as safety assessing Member State for an active substance used in multinational clinical trials since 31 January 2022.


Austria 110
Austria 116
Belgium 216
Bulgaria 69
Croatia 23
Cyprus 2
Czechia 119
Denmark 159
Estonia 18
Finland 61
France 279
Germany 251
Greece 79
Hungary 96
Ireland 50
Italy 242
Latvia 13
Lithuania 19
Netherlands 234
Norway 64
Poland 181
Portugal 79
Romania 77
Slovakia 48
Slovenia 13
Spain 296
Sweden 112
0 50 100 150 200 250 300 350

Annex

Annex I - Glossary

Term	Abbreviation	Definition
Clinical Trials Regulation	CTR	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
Clinical Trials Directive	CTD	Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
Clinical trial application	CTA	Initial clinical trial applications, substantial modification applications, applications to add an additional Member State Concerned are all considered as 'clinical trial applications'.
Initial CTA/Initial application		Initial application of a clinical trial in at least one Member State Concerned.
New initial clinical trial application/New initial application		Initial application of a clinical trial and not marked as a transitioned or resubmitted trial.
Transitioned clinical trial		Clinical trial previously authorised under the CTD, then transferred to the CTR by means of a simplified procedure via CTIS so to be compliant with the CTR.
Resubmitted clinical trial application		Resubmission of an initial clinical trial application for authorisation to a Member State Concerned, after the refusal to grant an authorisation or the withdrawal of an application by the sponsor.
Substantial Modification	SM	Any change to any aspect of a clinical trial, which is made after the notification of a decision on a previously submitted clinical trial application and which is likely to either have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the CT. In all cases, a modification is regarded as 'substantial' when one or both of the above criteria are met. In principle, it is the responsibility of the sponsor to judge whether a modification is to be regarded as 'substantial' or not. This

		judgement is to be made on a case-by-case basis.
Additional Member State Concerned	AddMSC	The extension of a clinical trial to another Member State Concerned territory and subjects
Clinical Trial	CT	Clinical study which fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within the normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects."
Clinical Trial with a decision		Clinical Trial where at least one MS has issued a decision `Authorised', `Authorised with conditions' or `Not authorised'. In the KPI report, CT Halted and Ended are included in this classification. (CT Status considered: Authorised, Ended, Halted, Not authorised, Revoked).
Multinational clinical trial		A clinical trial for which the sponsor submitted an application dossier to more than one Member State.
Mononational clinical trial		A clinical trial for which the sponsor submitted an application dossier to one Member State.
Commercial clinical trial		A clinical trial for which the primary sponsor is a commercial sponsor.
Non-Commercial clinical trial		A clinical trial for which the primary sponsor is a non-commercial sponsor.
Clinical Trial Information System	CTIS	The IT platform, consisting of the EU portal and EU database, and the safety module that allows the exchange of clinical trials information in the European Union.
Member State concerned	MSC	A Member State that has received an application of a clinical trial intended to be conducted in its territory, or a modification of a previously submitted clinical trial application for its assessment, and therefore is responsible for the evaluation of the positive benefit/risk of that clinical trial.

Reporting Member State	RMS	Member State Concerned with a leading role during the clinical trial lifecycle that performs several tasks including the lead assessment (or creating the draft assessment report), raising and consolidating considerations during the validation and Part I assessment phases, and including conclusions on Part I.
Ongoing clinical trial		A trial that has received a positive decision in EU/EEA, it is started in at least one MSC and it is not ended in all the MSCs.
Transition period		The CTR is applicable in the EU/EEA since 31 January 2022 and has a three-year transition period. This transition period is as follows: • Until 30 January 2023 sponsors have had the chance to submit new initial clinical trial applications under the CTR via CTIS or the CTD via EudraCT; • From 31 January 2023 all new initial clinical trial applications must be submitted under the CTR; • As of 31 January 2025 only the CTR applies to all clinical trials also to those trials previously authorised under the CTD.
CT Authorised		Clinical trial for which the first MSC submits 'Authorised' or 'Authorised with conditions' to the initial application or if all the MSCs have submitted their decision, and at least one has submitted 'Authorised 'or 'Authorised with conditions'.
CT Ended		Clinical trial whose status in all MSCs is 'Ended'. This means that at some point, the clinical trial was authorised in these MSCs.
CT Halted		Clinical trial authorised with an interruption, in all MSCs, not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it.
CT Lapsed		Clinical trial for which the sponsor has not provided responses to the RFI(s) with the timelines stipulated by the RMS (for Part I RFI) or where the sponsor does not apply for an authorisation limited to aspects covered by Part II documents within two years from the conclusion Part I in all MSCs.
CT Not authorised		Clinical trial for which all the MSCs have submitted their decision and they have all selected 'Not authorised'.
CT Not valid		Clinical trial for which the RMS considers the initial clinical trial application dossier as not

		complete, or that the clinical trial application does not fall within the scope of the Regulation (EU) No 536/2014.
CT Under evaluation		Clinical trial for which the initial clinical trial application has been submitted in at least one MSC and for which none of the MSC(s) has issued a decision yet.
CT Withdrawn		Clinical trial for which the initial clinical trial application has been withdrawn by the sponsor in all MSCs.
Advanced therapy medicinal products	ATMP	An ATMP is defined as either a gene therapy 'medicinal product' (GTMP), a somatic cell therapy 'medicinal product' (sCTMP) or a tissue-engineered product (TEP).
Part I conclusion		Conclusions concerning the aspects addressed in Part I of a clinical trial application. This is issued by the RMS.
Part II conclusion		Conclusions concerning the aspects addressed in Part II of a clinical trial application. This is issued by each MSC individually.
Safety assessing Member State	saMS	The Member State that assesses the information submitted as suspected unexpected serious adverse reactions in accordance with Article 42 of the Clinical Trials Regulation (EU) No 536/2014, and the information contained in annual safety reports submitted in accordance with Article 43 of that Regulation, for clinical trials involving investigational medicinal products that contain the same active substance, regardless of the pharmaceutical form and strength or indication investigated and regardless of whether they are used in one or several clinical trials managed by the same or different sponsors.

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000
Send a question www.ema.europa.eu/contact

www.ema.europa.eu

Monitoring the European clinical trials environment - July 2026
EMA/170274/2026