European Commission

EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

Monitoring the European clinical trials environment

A deliverable of the ACT EU Priority Action 2

September 2024

An agency of the European Union

Clinical Trials in the EU/EEA

September 2024

807

+20 %
on previous month

Submissions

650

+8 %
on previous month

Authorised

229 Multinational	
50 Non-Commercial	**179** Commercial
578 Mononational	
479 Non-Commercial	**99** Commercial

247 Multinational	
37 Non-Commercial	**210** Commercial
403 Mononational	
311 Non-Commercial	**92** Commercial

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 month of September 2024, as of 30 September 2024, as well as cumulative numbers since the launch of CTIS on 31 January 2022.

Since the mandatory use of CTIS for initial clinical trial applications, 31 January 2023, the average submission of clinical trials applications, of any type, has seen a significant increase, averaging more than 385 submissions per month.

A total of 8,407 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 3,700 initial clinical trials are ongoing in EU/EEA under the CTR.

The therapeutic area mostly investigated is Neoplasms (Tumour).

Contents

Chapter 1

Submitted initial clinical trial applications

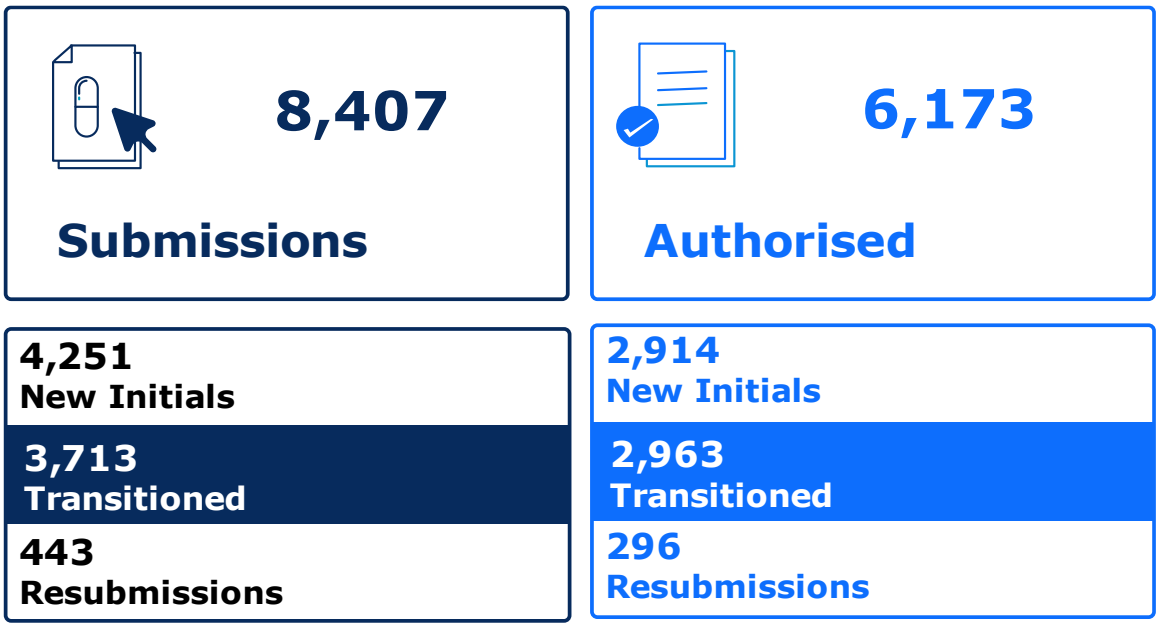
Chapter 1 of this report provides information on **submitted** initial clinical trial applications (CTAs), presented on the applicable statuses.

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

Initial clinical trial applications are those applications:

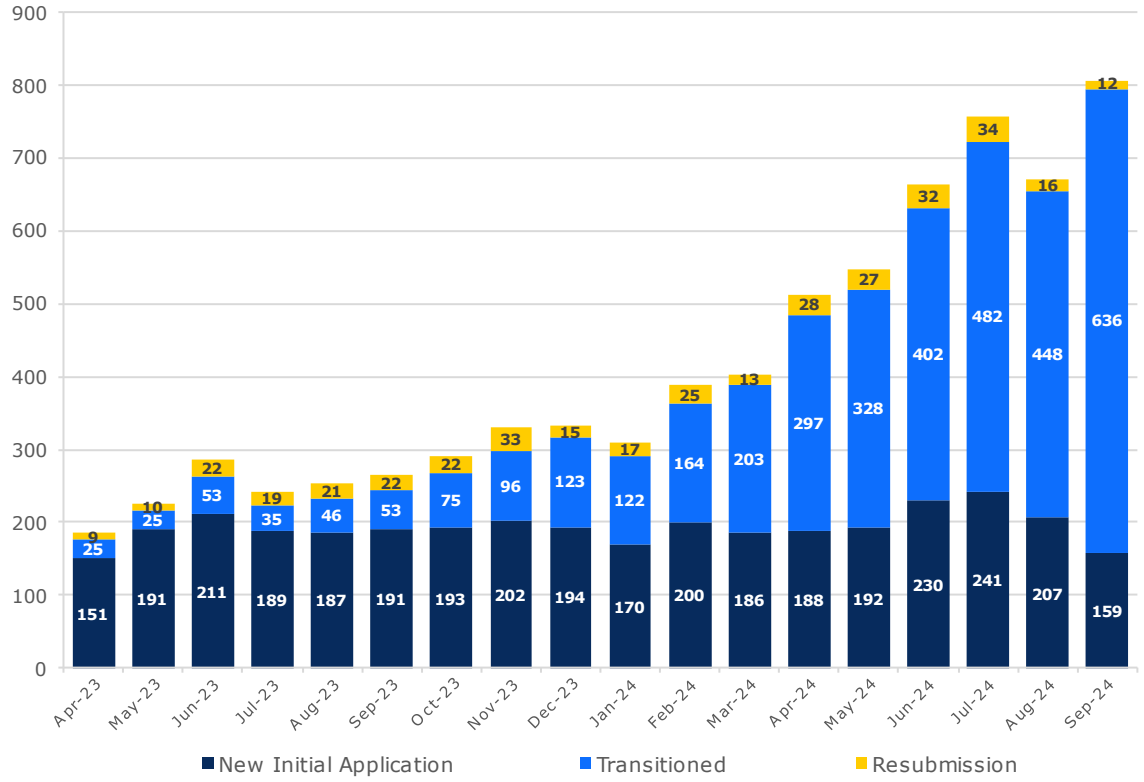
- new initial clinical trial applications submitted in CTIS by the sponsors under the Clinical Trials Regulation (EU) 536/2014 (CTR);
- trials which were already authorised under the regime of Clinical Trials Directive 2001/20/EC (CTD) and that have been transitioned to the regime of CTR;
- resubmitted 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")*.



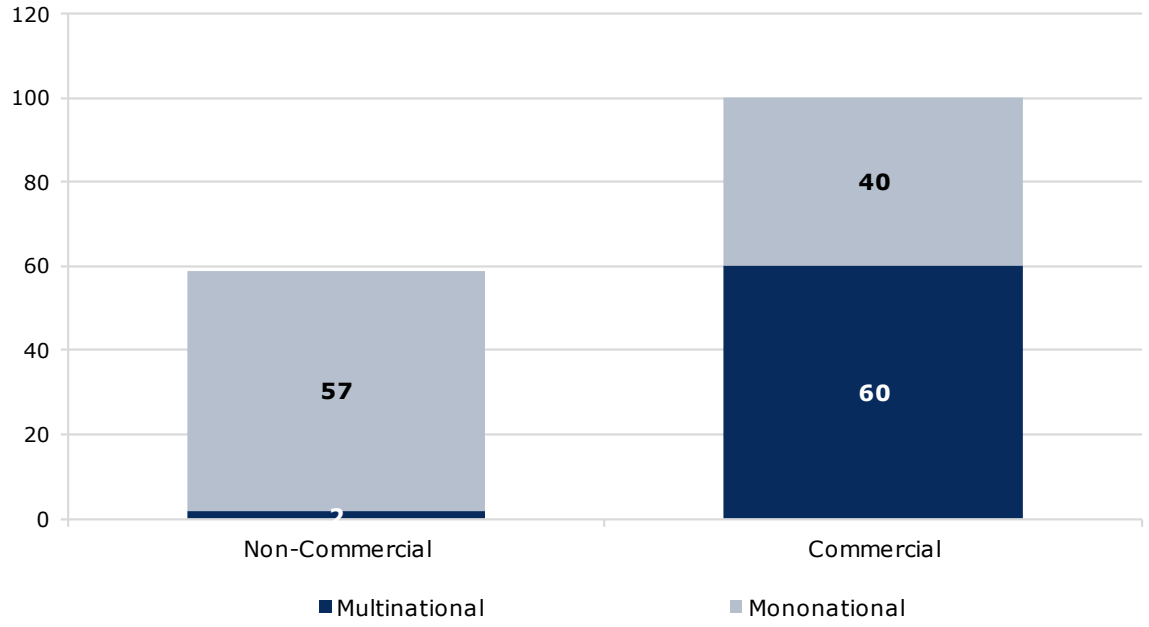
Monthly submissions of initial clinical trial applications

In September 2024, 807 initial clinical trial applications have been submitted, of which 159 new initial CTA, 636 are trials transitioned to CTR, and 12 are resubmissions of previously submitted initial applications *(the graph below shows the data for the last 18 months)*.



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

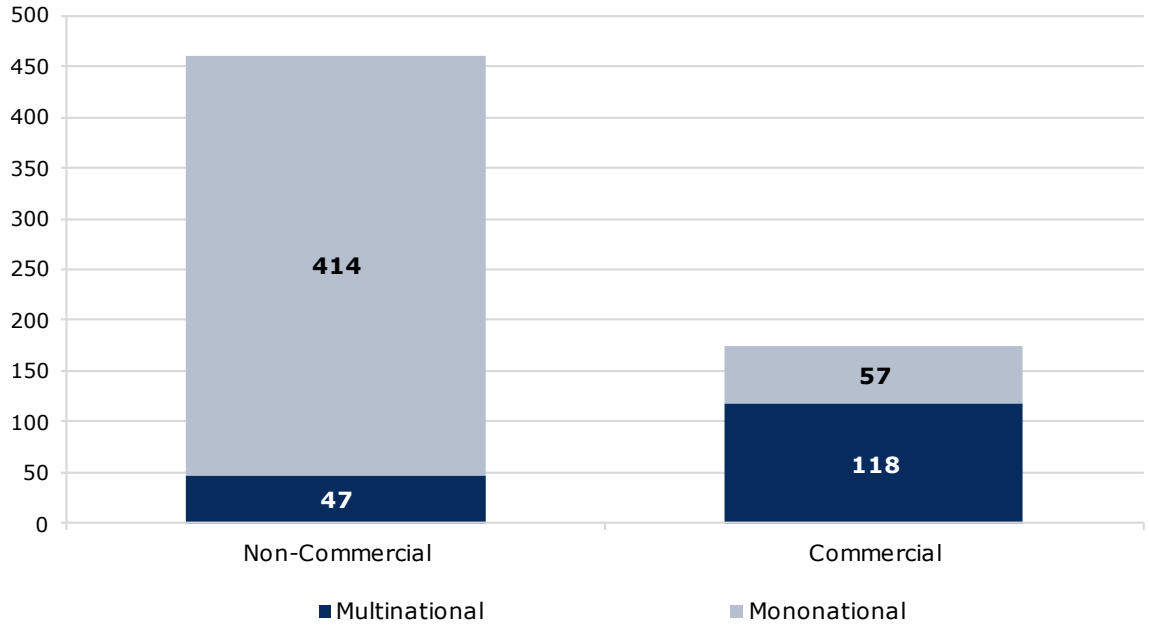
The graph below shows the split of submissions of new initial clinical trial applications in September 2024 into commercial/non-commercial sponsors and mononational versus multinational trials.



Clinical trials transitioned from CTD to CTR per sponsor type and mono- vs multinational trials

Since 31 January 2022 the CTR repealed the Clinical Trial Directive 2001/20/EC (CTD) and a 3-year transition period is foreseen from the implementation of the CTR. During this period, sponsors have to transition those clinical trials that are planned to continue after the end of the transition period. From 31 January 2025 onwards, all clinical trials have to follow the regime of the CTR.

The graph below shows the split of submissions of transitioned clinical trials in September 2024 into commercial/non-commercial sponsors and mononational versus multinational trials.

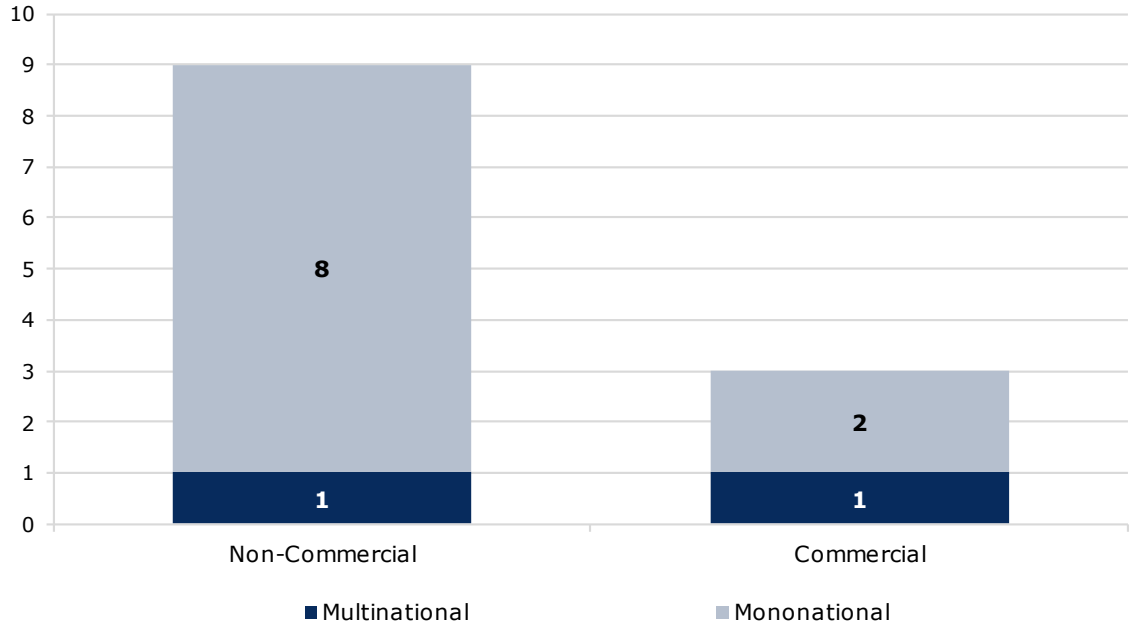


Once notified by the clinical trial sponsors, the National Competent Authorities of the EU/EEA Member States are responsible for keeping, in the EudraCT database, the information on the trial status up to date, including inserting the end of trial date, as applicable.

*Further information can be found under **Annex I**.*

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 September 2024 into commercial/non-commercial sponsors and mononational versus multinational trials.



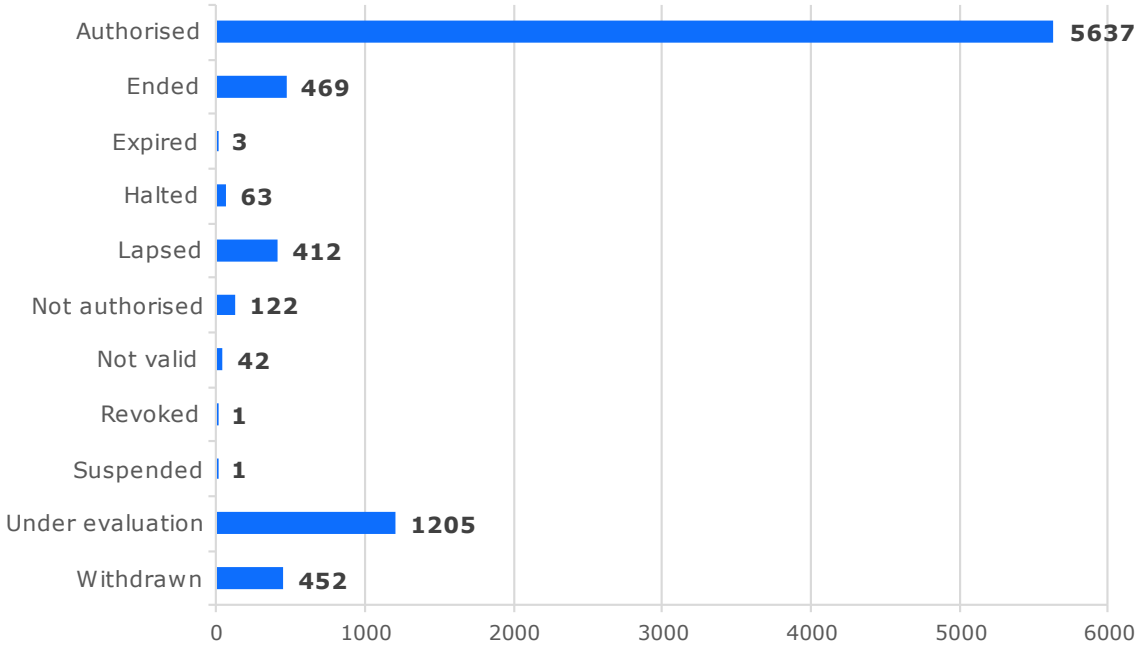
Clinical trials per applicable statuses

Since 31 January 2022, a total of 8,407 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**.

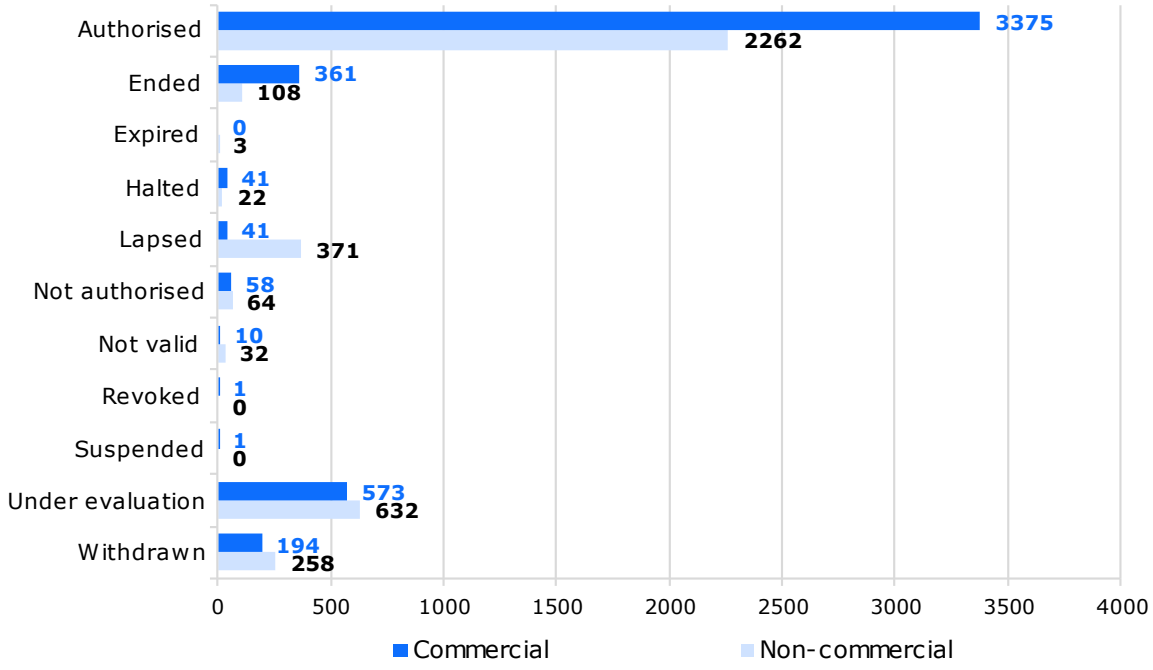
Clinical trials per applicable statuses

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/multi-national trials, as Reporting Member State (RMS)[1] 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)].

Member State	Multinational Trials		Mononational Trials	Total number of Initial CTAs
	MSC	*Of which as RMS*		
Austria	297	50	41	338
Belgium	596	112	205	801
Bulgaria	302	4	22	324
Croatia	99	0	0	99
Cyprus	4	0	1	5
Czechia	458	86	45	503
Denmark	330	101	216	546
Estonia	56	5	6	62
Finland	130	37	37	167
France	1041	160	416	1457
Germany	1064	334	307	1371
Greece	283	2	14	297
Hungary	425	23	20	445
Iceland	8	0	1	9
Ireland	109	10	14	123
Italy	1008	119	141	1149
Latvia	55	5	4	59
Lithuania	69	10	4	73
Luxembourg	2	0	1	3
Netherlands	508	114	328	836
Norway	138	22	44	182
Poland	829	90	73	902
Portugal	223	13	64	287
Romania	244	10	27	271
Slovakia	161	16	2	163
Slovenia	28	2	2	30
Spain	1314	387	321	1635
Sweden	255	61	101	356

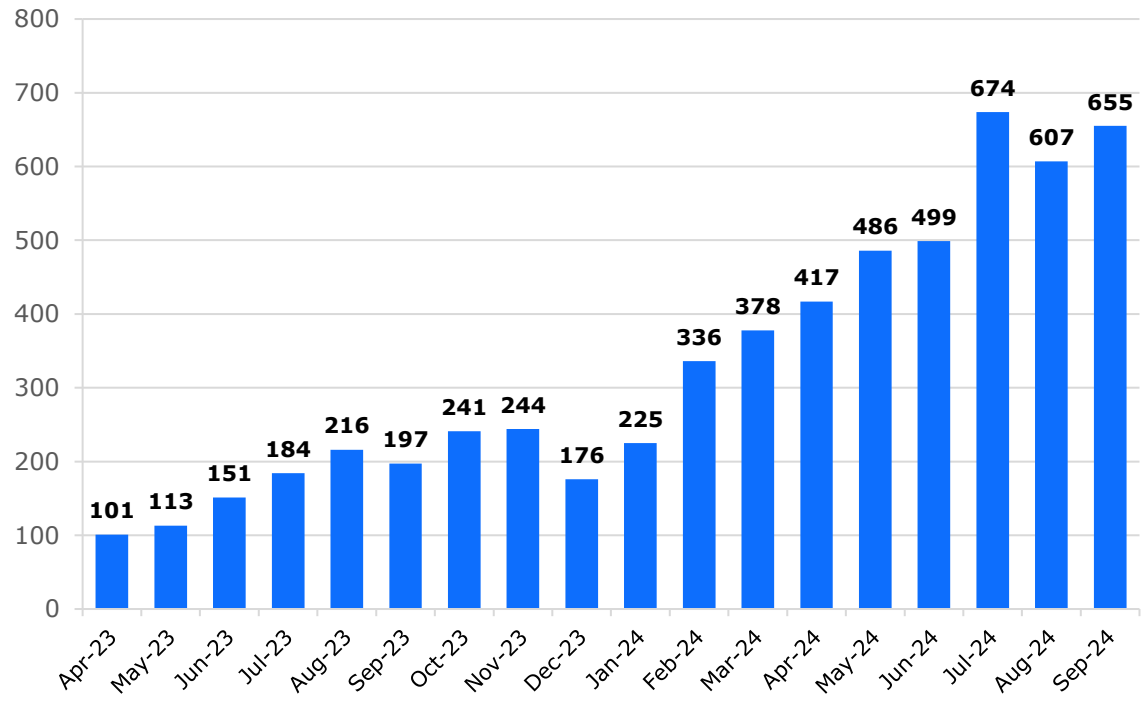
[1] RMS is the Reporting Member State appointed in line with the requirements of Article 5 of the Clinical Trials Regulation (EU) No 536/2014.

Chapter 2

Authorised clinical trials

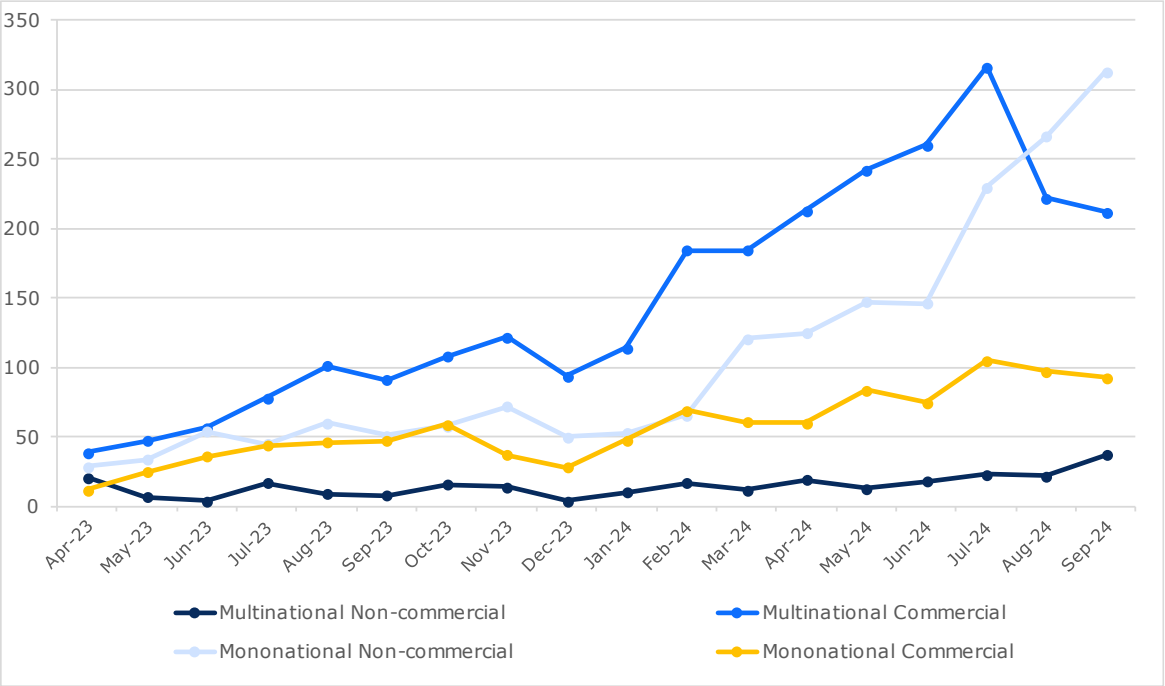
Since 31 January 2022, a total of 6,296 have received a decision in CTIS, of which 6,173 received a positive decision authorising the clinical trial. The graph below includes figures on both authorised and not authorised clinical trials in the last 18 months.

In September 2024, of the 655 initial clinical trial with a decision, 650 have been authorised.



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.

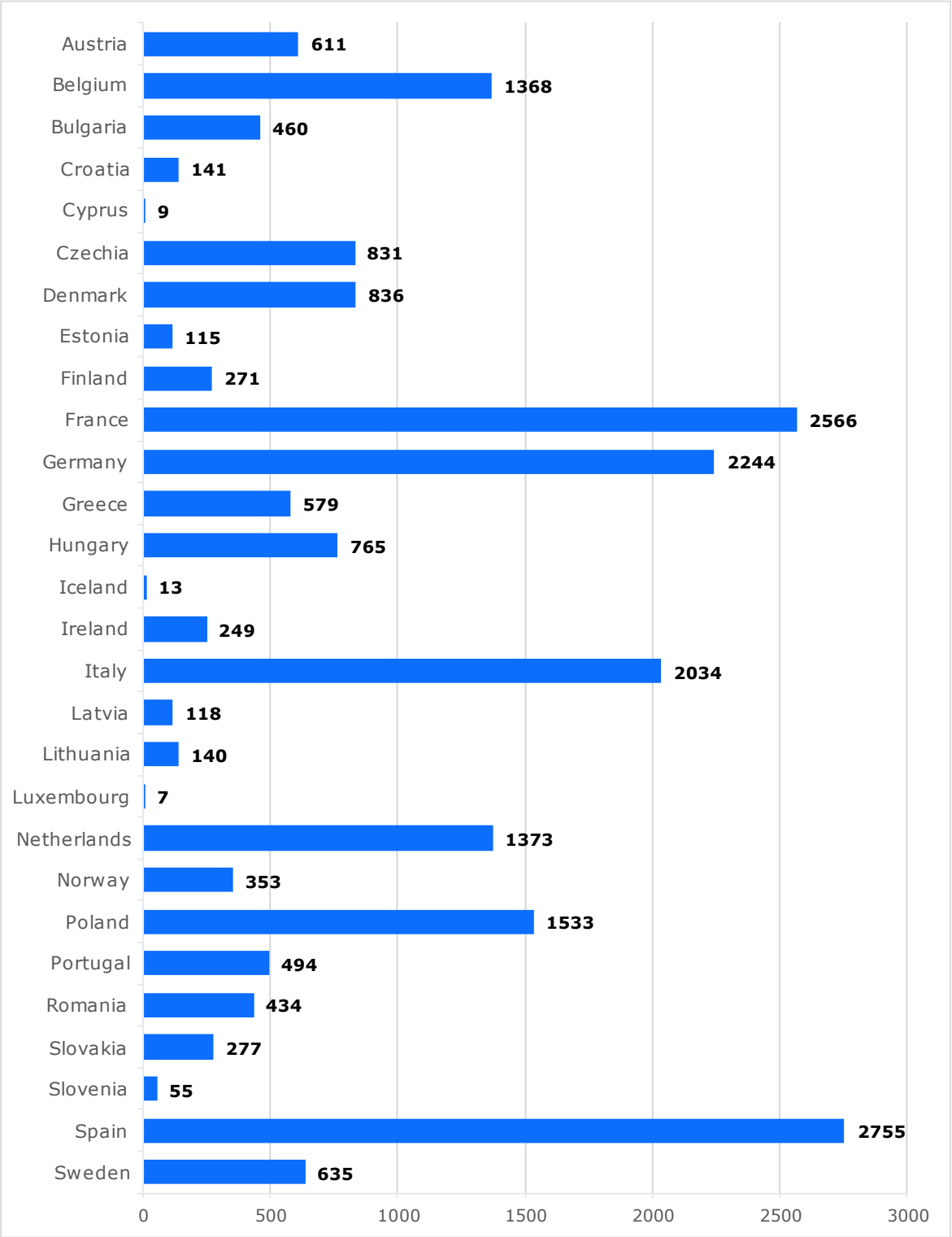


Until September 2024, 3,206 multinational clinical trials have a decision in CTIS with an average of 6 Member States Concerned.

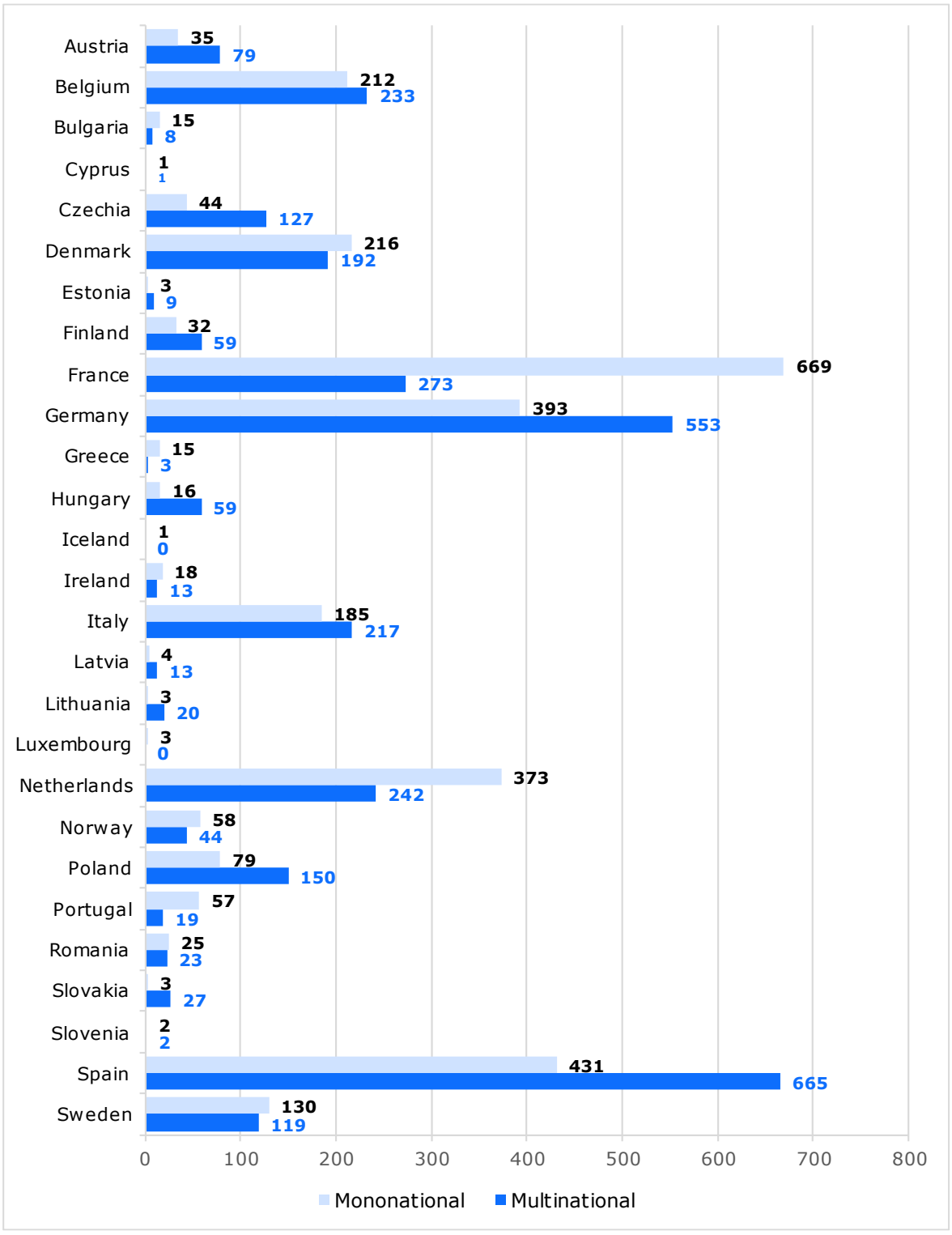
Distribution of **authorised** clinical trials per Member State Concerned and appointment of Reporting Member State

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 States Concerned[2] in an initial clinical trial application even if it has not authorised yet the trial in its country.

[2] 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.



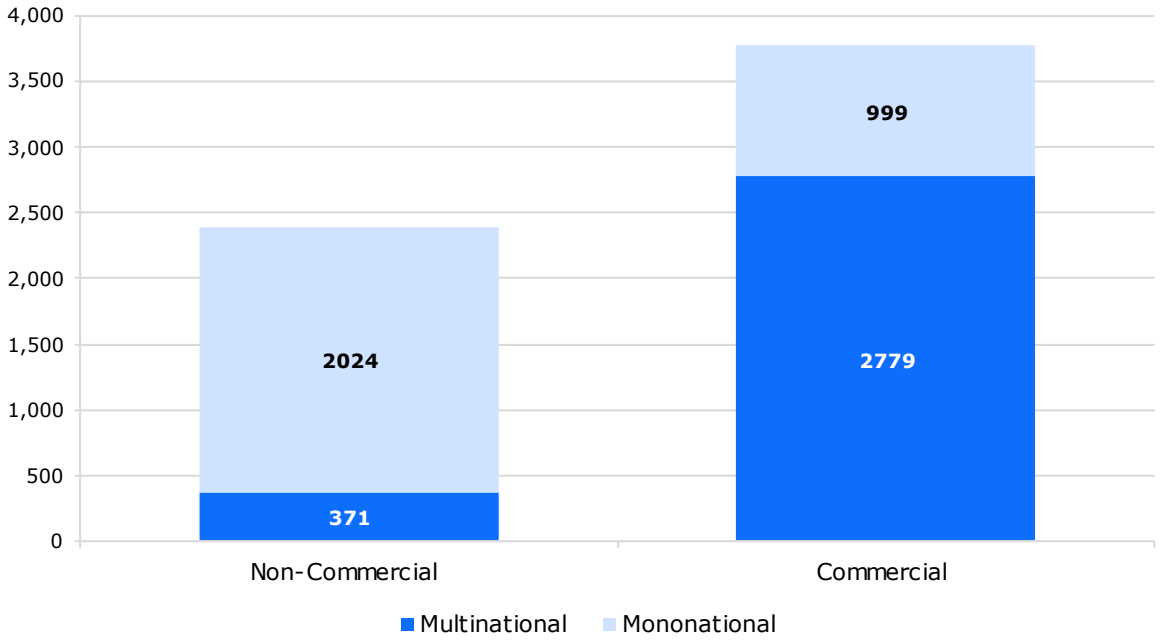
The graph below shows the distribution of appointment of Reporting Member State (RMS), amongst the applicable Member States Concerned, in authorised mono- and multinational trials.


Austria 35 79
Belgium 212 233
Bulgaria 15 8
Cyprus 1 1
Czechia 44 127
Denmark 216 192
Estonia 3 9
Finland 32 59
France 669 273
Germany 393 553
Greece 15 3
Hungary 16 59
Iceland 1 0
Ireland 18 13
Italy 185 217
Latvia 4 13
Lithuania 3 20
Luxembourg 3 0
Netherlands 373 242
Norway 58 44
Poland 79 150
Portugal 57 19
Romania 25 23
Slovakia 3 27
Slovenia 2 2
Spain 431 665
Sweden 130 119
0 100 200 300 400 500 600 700 800
Mononational
Multinational

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

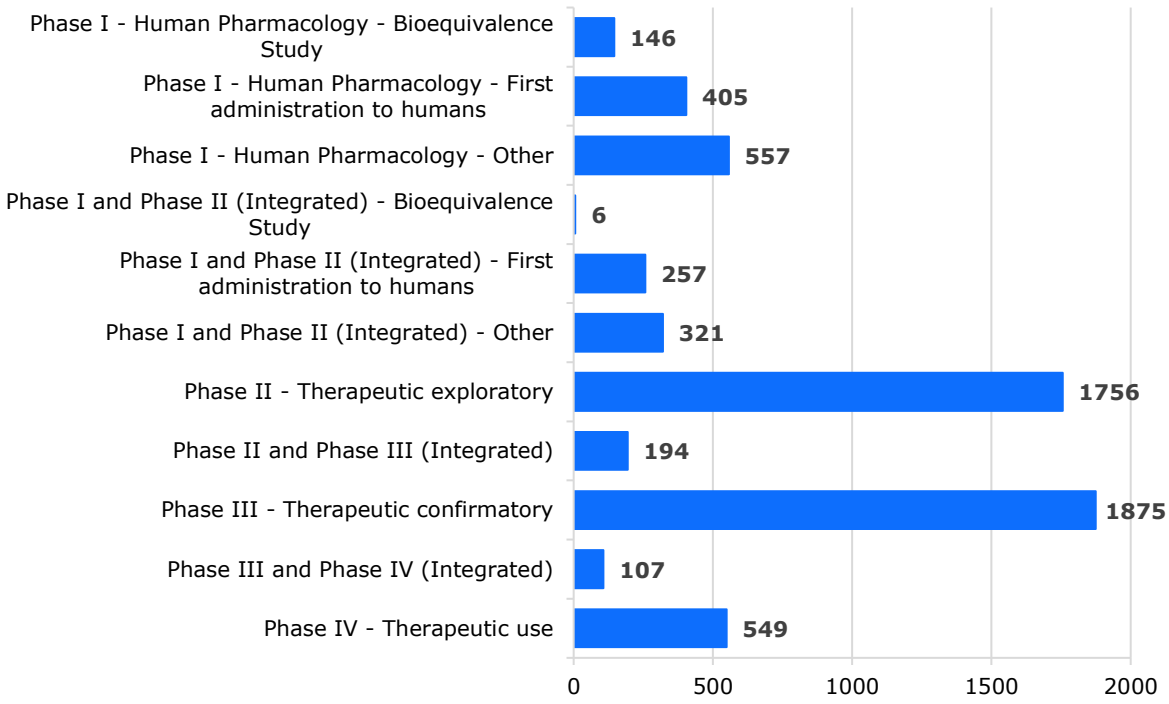
The graph below shows the number of clinical trials authorised since 31 January 2022, split into mono national/ multi-national and per sponsor type.

The graph shows a majority of mono-national CTs authorised conducted by non-commercial sponsors. On the contrary the majority of CTs authorised, 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 early (I and II))

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

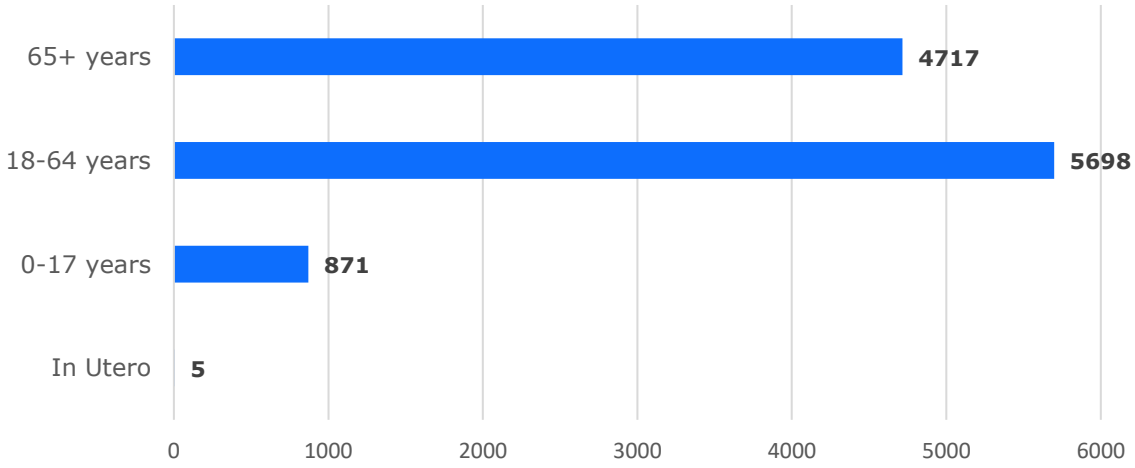


Clinical trials per population type and rare disease

At the end September 2024, 3,701 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[3].

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

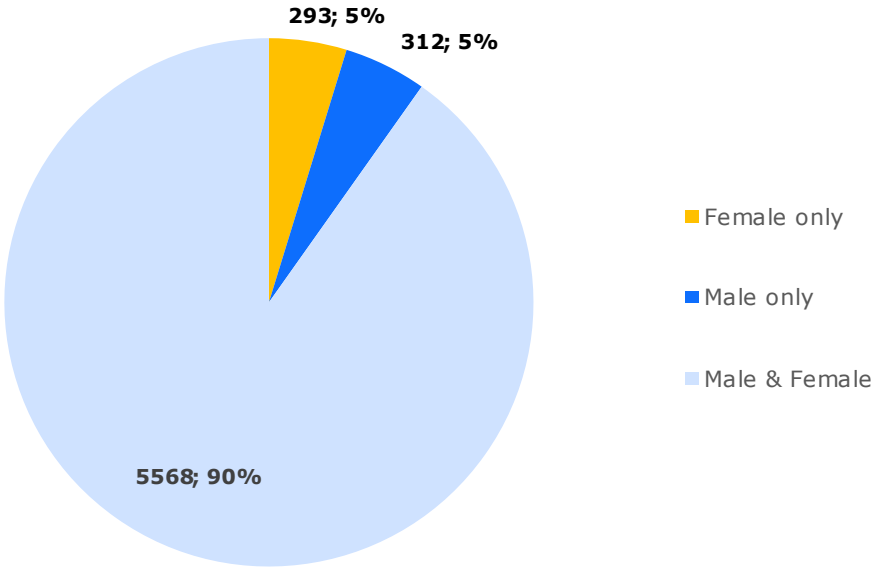
By Age of clinical trials participants



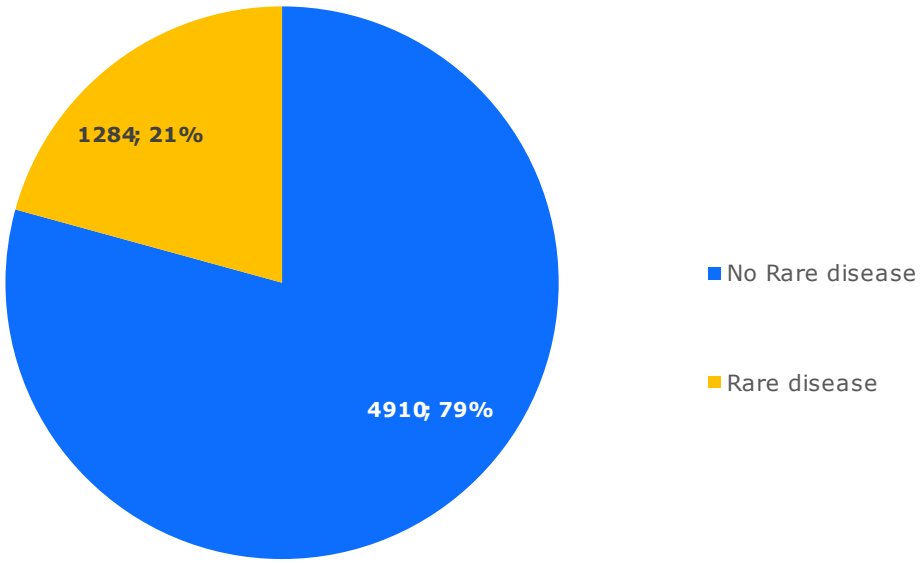
[3] Details on recruitment status are based on the information reported by the trial sponsor in CTIS.

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

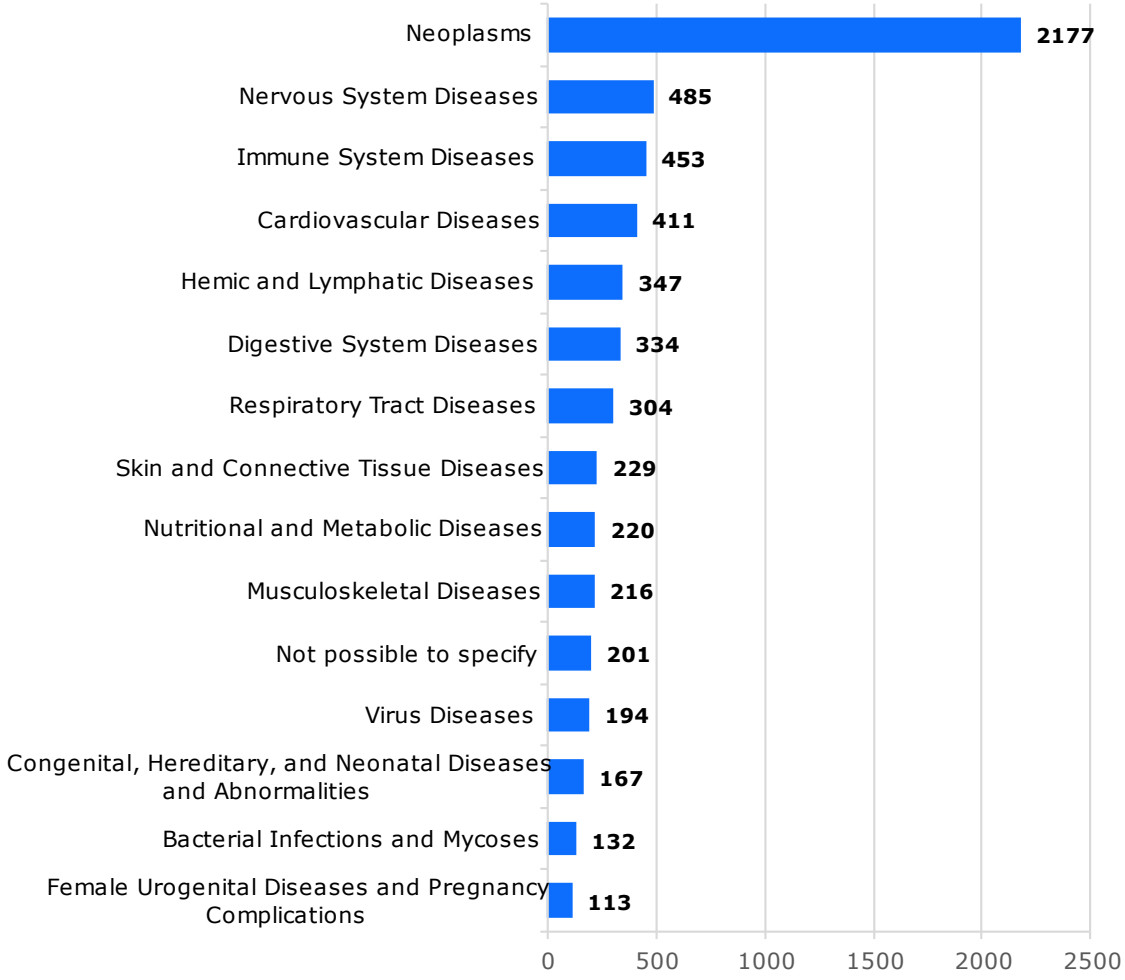


It is important to note that more than one disease could be investigated in one clinical trial (e.g., a clinical trial may be for a rare disease as well as for No rare disease and in this case it

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

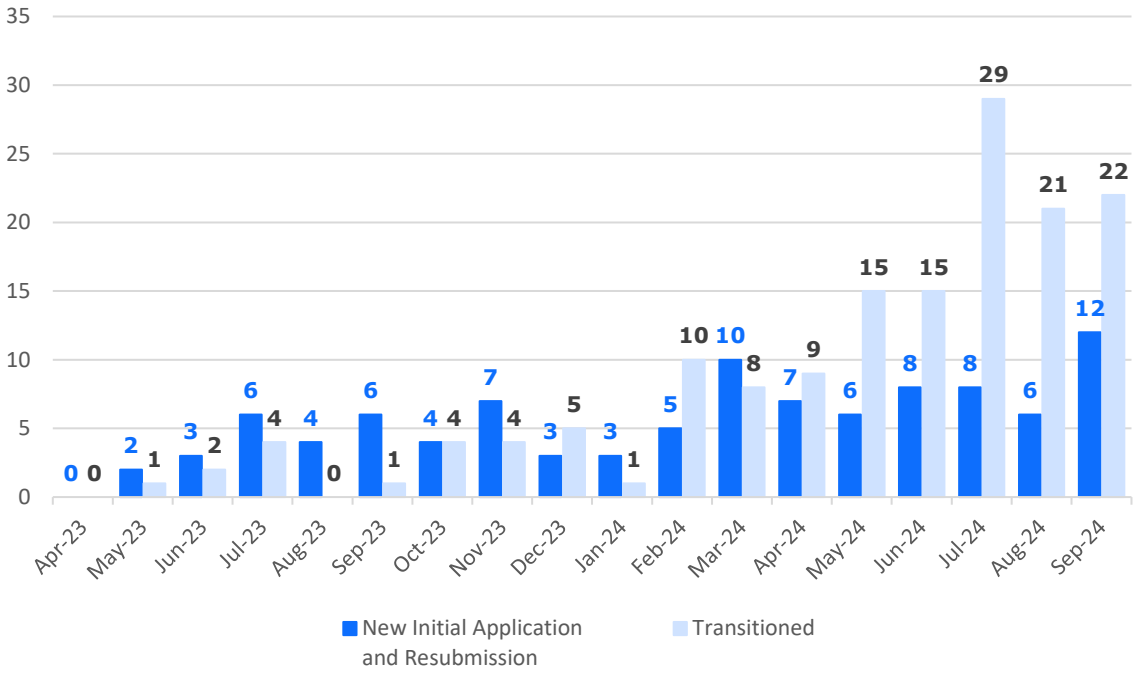
The graph below shows the number of clinical trials authorised since January 2022, broken down per therapeutic area[4], showing the most frequent 15 therapeutic areas.



Authorised clinical trials with an ATMP

Thirty-four clinical trials with an Advanced Therapy Medicinal Product (ATMP) have been authorised in September 2024, bringing the total of authorised clinical trials with ATMP to 269, as illustrated in the graph below *(the graph below shows the data for the last 18 months)*.

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


35
30
25
20
15
10
5
0
0 0
2 1
3 2
6 4
4 0
6 1
4 4
7 4
3 5
3 1
5 10
10 8
7 9
6 15
8 15
8 29
6 21
12 22
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Oct-23
Nov-23
Dec-23
Jan-24
Feb-24
Mar-24
Apr-24
May-24
Jun-24
Jul-24
Aug-24
Sep-24
New Initial Application and Resubmission
Transitioned

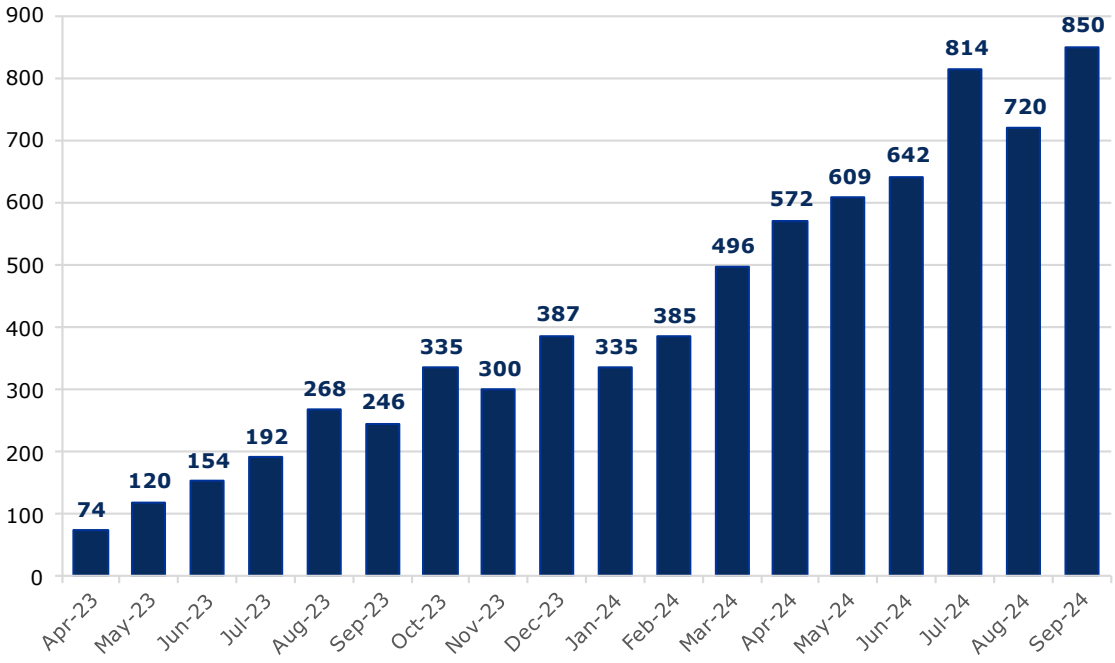
Chapter 3

Substantial modification applications

Substantial modifications[5] 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

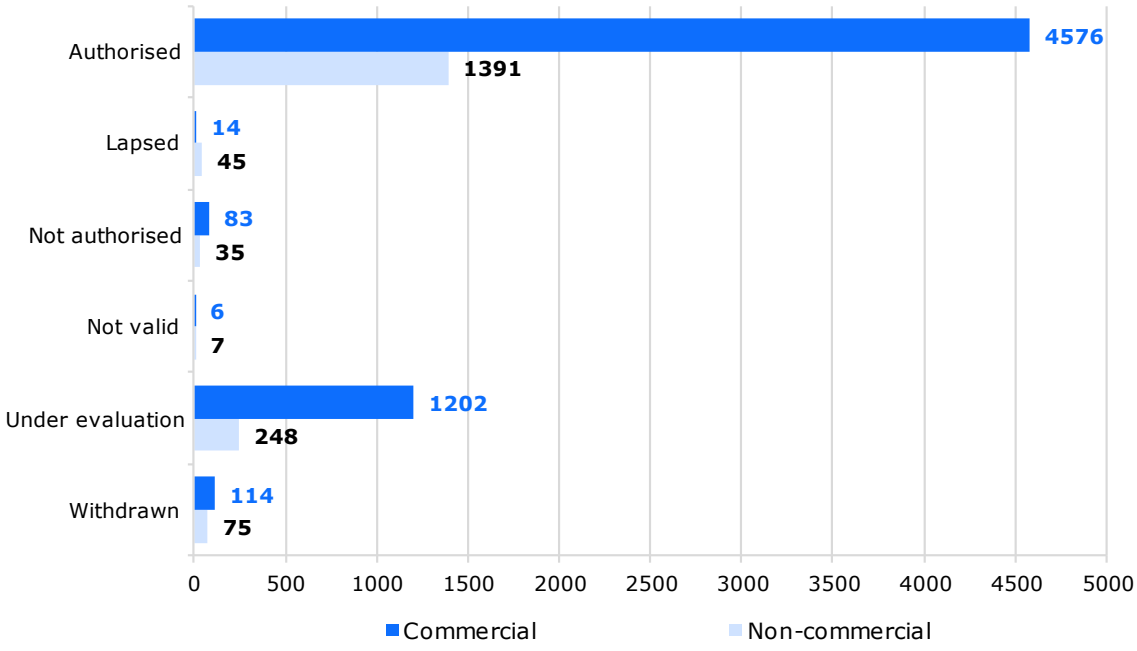
Overall, 7,796 distinct substantial modification applications, affecting 3,175 trials, have been submitted since the launch of the system on 31 January 2022, of which 850 substantial modifications submitted in September 2024, affecting 676 trials *(the graph below shows the data for the last 18 months)*.



Substantial modification applications per applicable statuses and by sponsor type

Since 31 January 2022, 7,796 distinct applications for substantial modifications, were submitted in CTIS, presented below per application status and sponsor type.

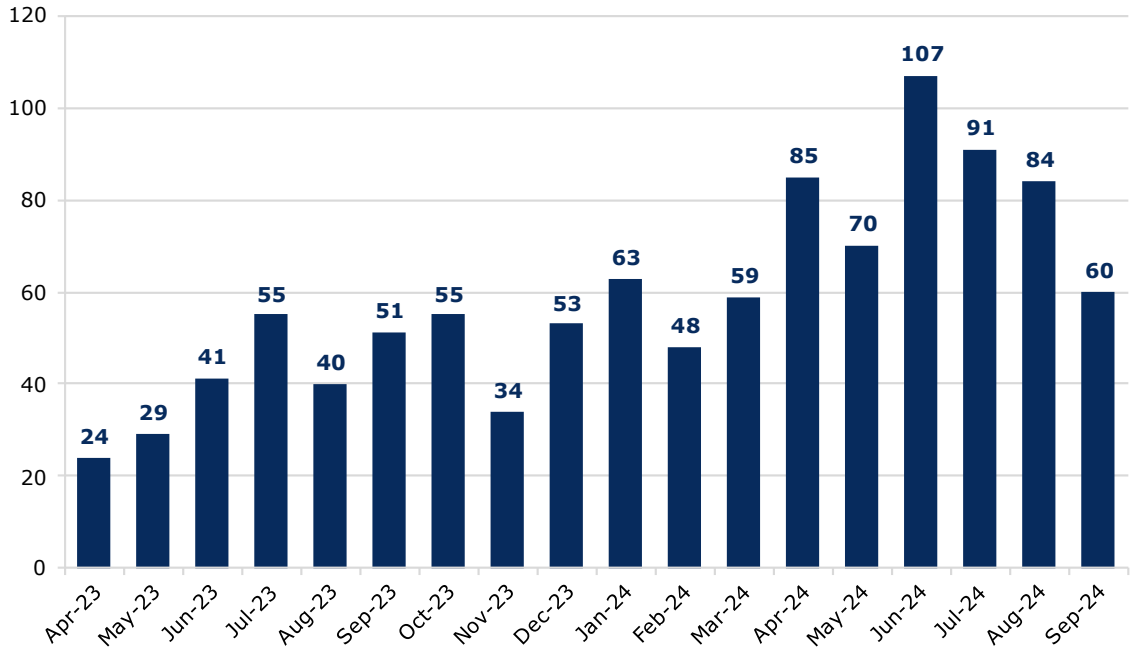
[5] Substantial modifications for part I only, or part II only or part I and part II, are foreseen in chapter II of Regulation (EU) No 536/2014


Authorised
4576
1391
Lapsed
14
45
Not authorised
83
35
Not valid
6
7
Under evaluation
1202
248
Withdrawn
114
75
0
500
1000
1500
2000
2500
3000
3500
4000
4500
5000
Commercial
Non-commercial

Chapter 4
Addition of a Member State Concerned

Submitted addition of Member States Concerned applications

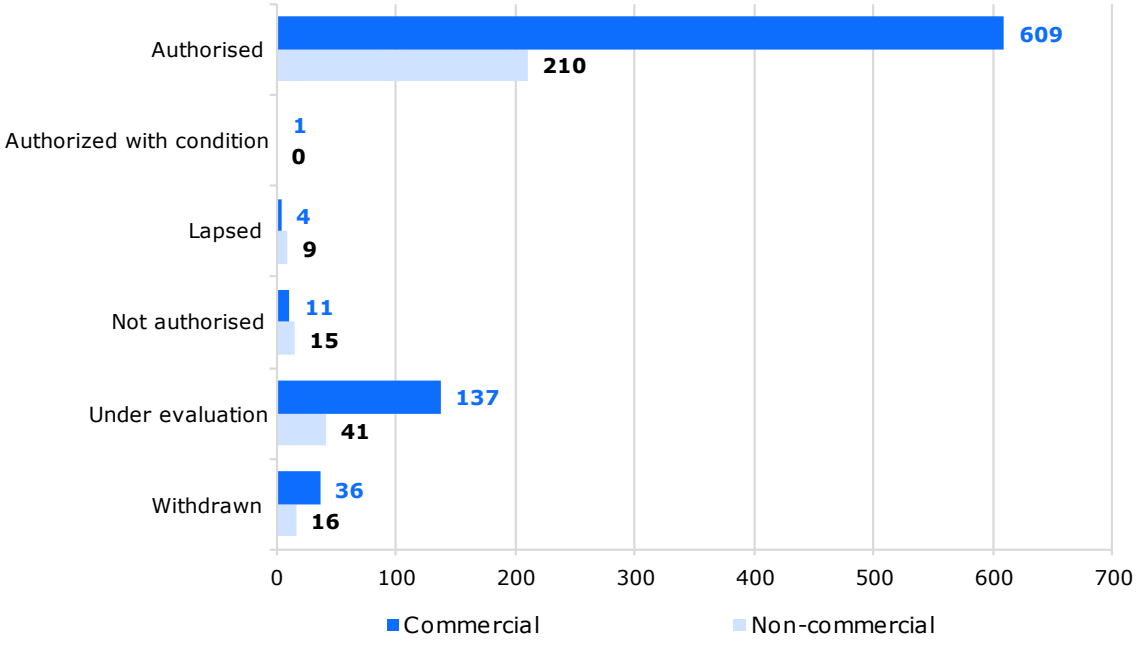
Since 31 January 2022, 1,089 distinct applications for the addition of a new MSC[6], affecting 429 trials, have been submitted in CTIS, of which 60 addition of new MSC submitted in September 2024, affecting 38 trials *(the graph below shows the data for the last 18 months)*.



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

Since 31 January 2022, 1,089 distinct applications for the addition of a new MSC have been submitted in CTIS, presented below per application status and sponsor type.

[6] 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
609
210
Authorized with condition
1
0
Lapsed
4
9
Not authorised
11
15
Under evaluation
137
41
Withdrawn
36
16
0
100
200
300
400
500
600
700
Commercial
Non-commercial

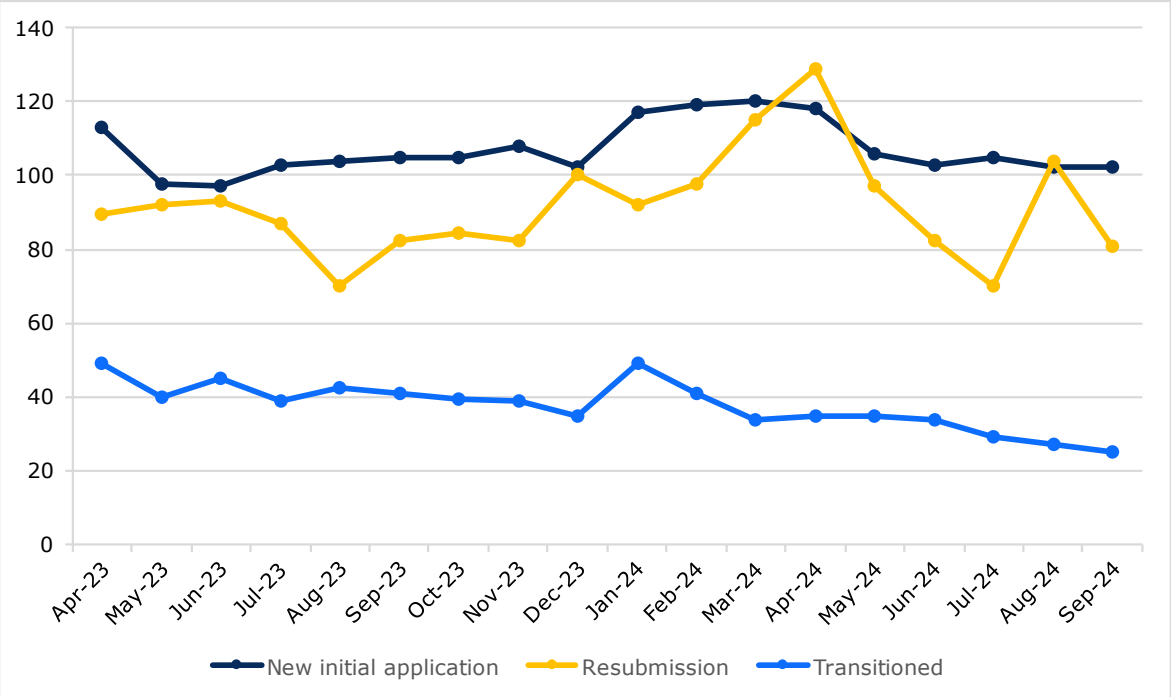
Chapter 5
Timelines

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

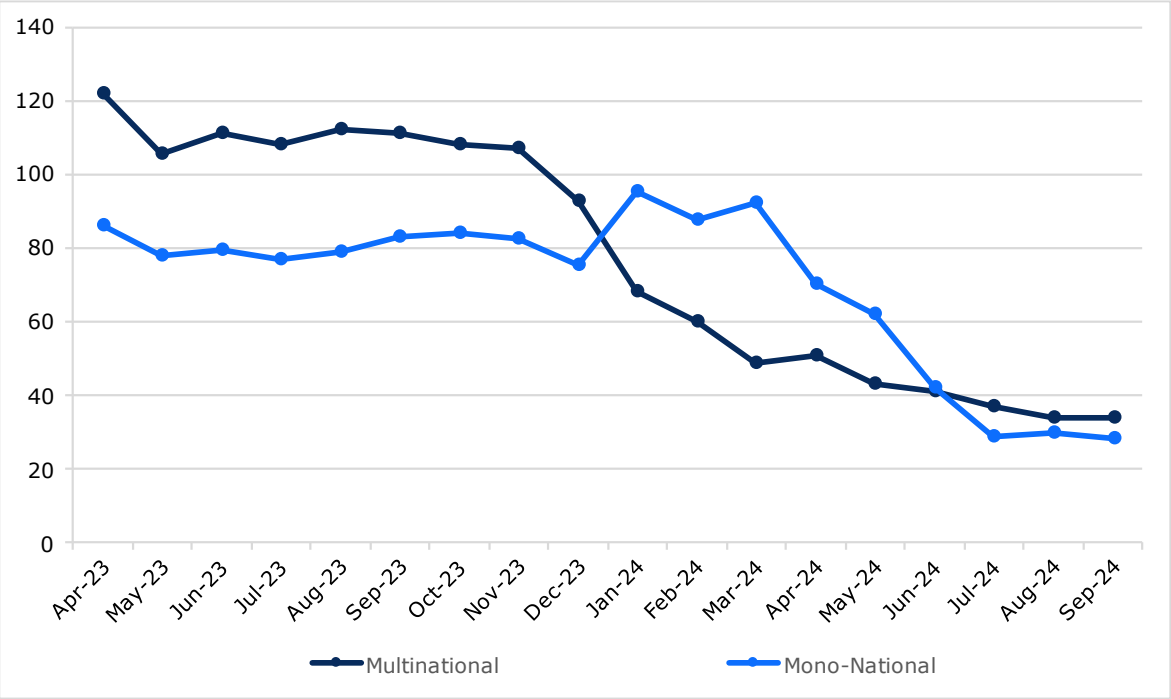
Median time from submission of initial clinical trial applications to decision

This graph takes into consideration the median number of days between the decision date, and the submission date for the trials for which the decision has been issued in that particular month. The time requested to issue a decision is related to the date when sponsors decide to submit Part II documents in case of partial initial application.

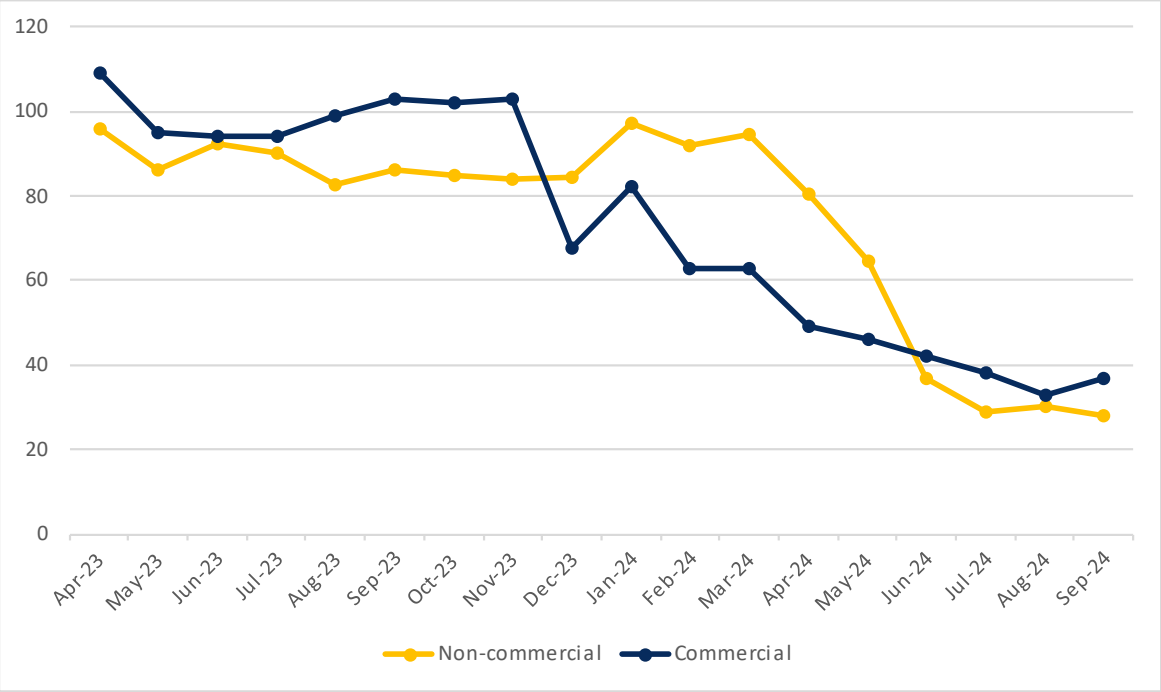
Median time per new initial application/ resubmission and transitional trials from submission of initial clinical trial applications to decision



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

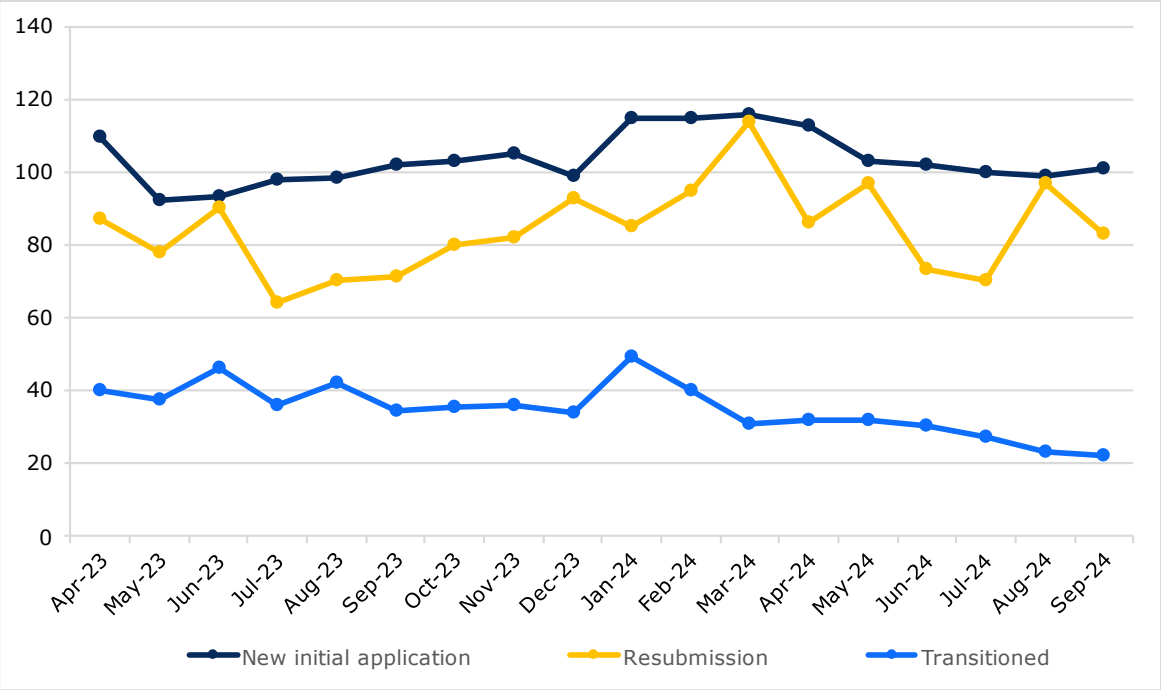


Median time per commercial/ non-commercial sponsors from submission of initial clinical trial applications to decision



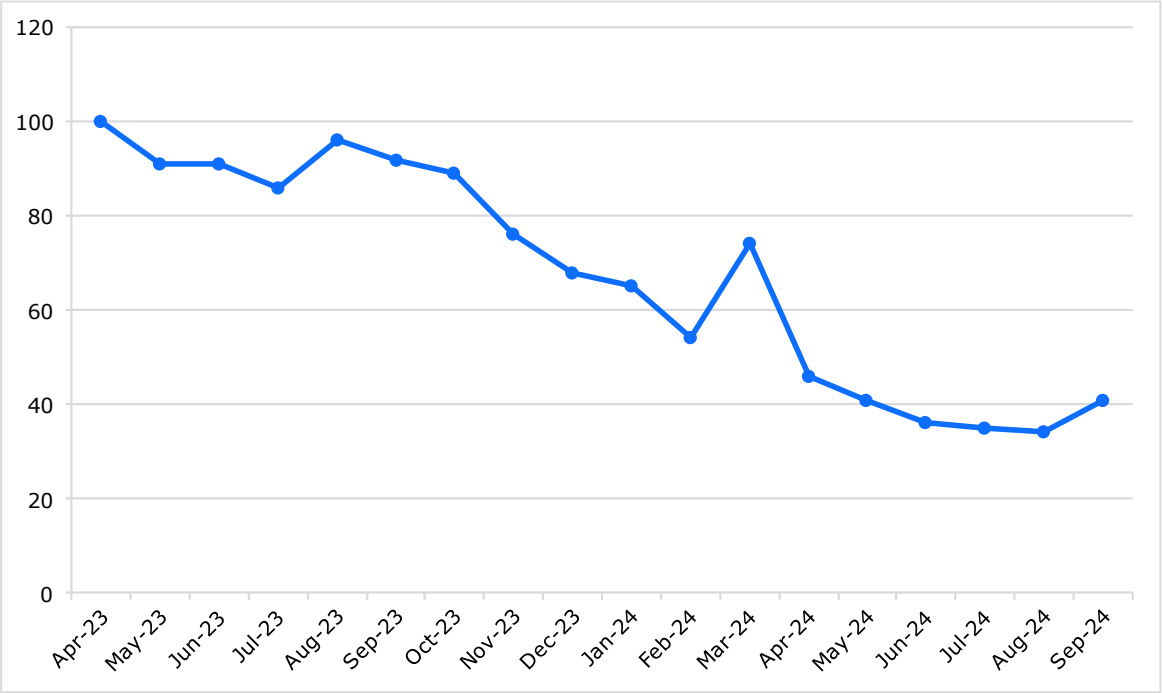
Median time from submission of initial clinical trial applications to Part I conclusion

This graph takes into consideration the median number of days between the part I conclusion and the submission date for the 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 part II conclusion, for each MSC, and the submission dates for the part I (regardless of whether the application was a full application or a partial application) for the trials for which the part II conclusion has been issued in that particular month. The time requested to reach part II conclusions depends on: (i) when conclusion on part I is issued, (ii) when sponsors submit part II documents and (iii) the time to assess part II documents and issue a part II conclusion. Sponsors are allowed to submit part II documents later than part I (still within 2 years after the notification of the conclusion on the aspects covered by Part I of the assessment report or the trial lapses – art. 11).


120
100
80
60
40
20
0
Apr-23
May-23
Jun-23
Jul-23
Aug-23
Sep-23
Oct-23
Nov-23
Dec-23
Jan-24
Feb-24
Mar-24
Apr-24
May-24
Jun-24
Jul-24
Aug-24
Sep-24

Chapter 6
Features of the substances

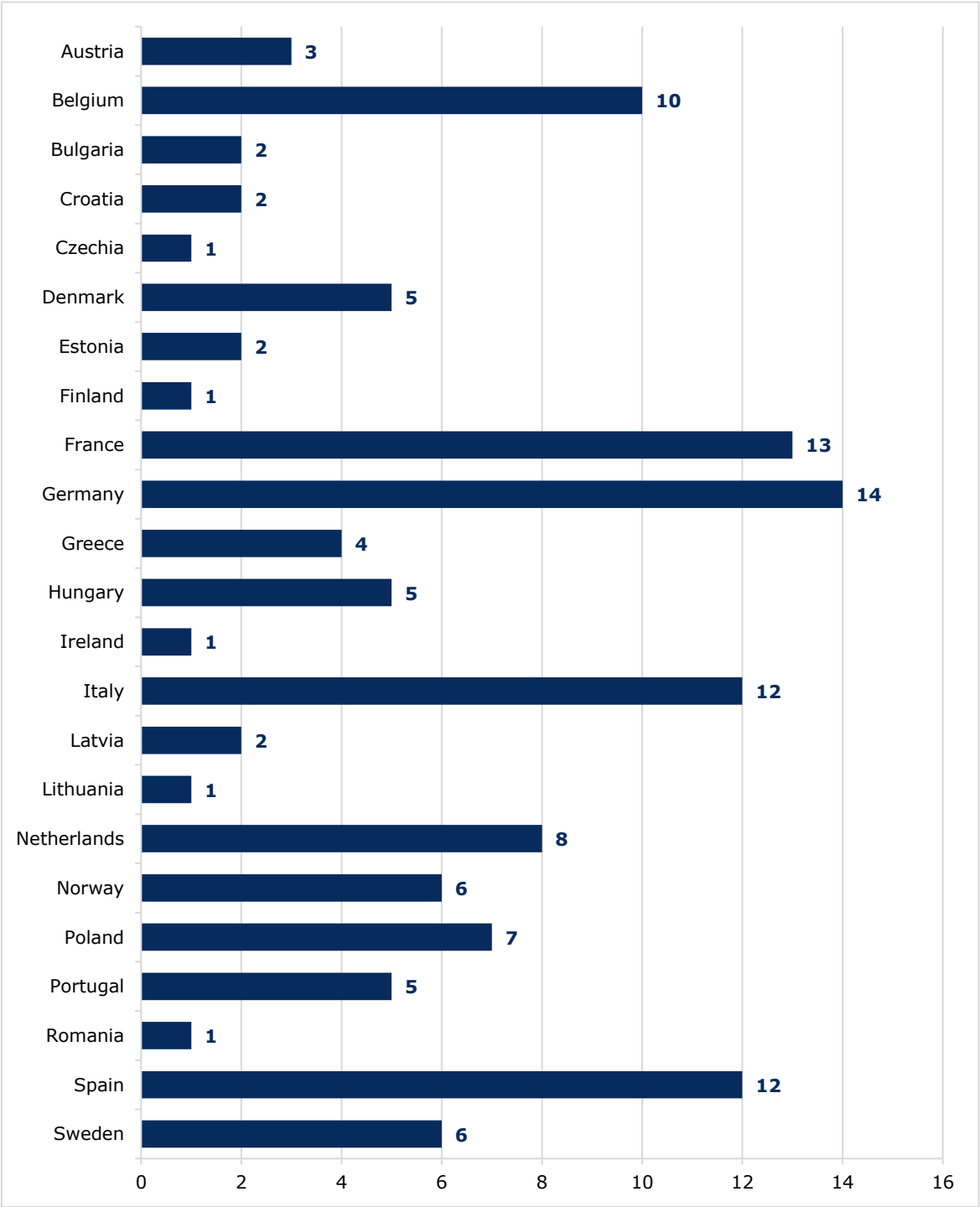
Safety assessing Member States (saMS) appointment

In multi-national clinical trials, the safety assessing Member State (saMS) is selected and responsible for the assessment of the safety report and relevant safety information of the active substances used, 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*.

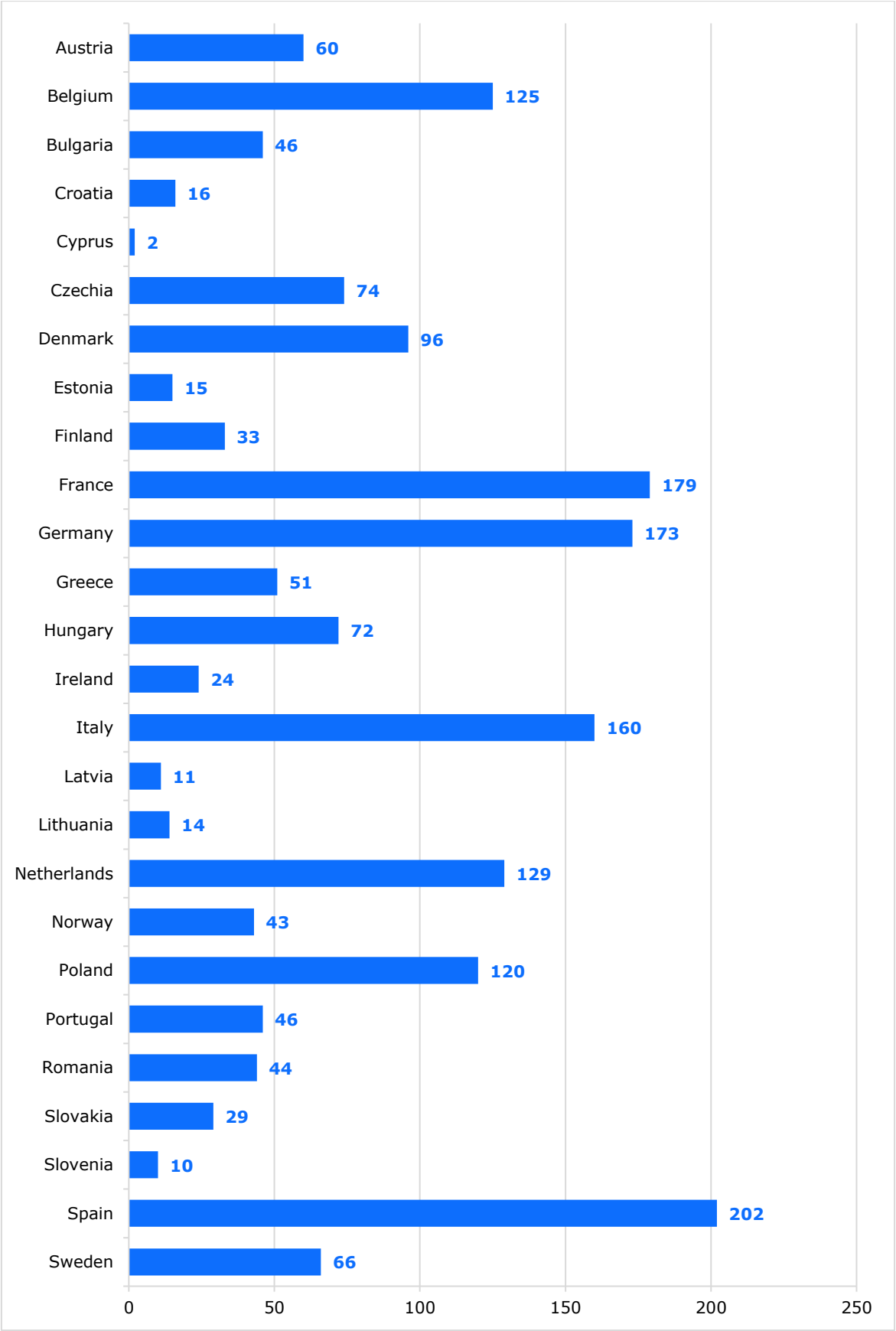
In mono-national clinical trial, the Member State is responsible for the assessment of information related to safety of active substances. Of note, the Implementing Regulation does not apply to mono-national active substances, to active substances in investigational medicinal products used as reference products, including as a placebo, or to active substances used in auxiliary medicinal products. Numbers are not displayed.

During the reporting period, Member States authorised application dossiers with 172 new active substances.

The graph below illustrates how many times each Member State has been appointed as safety assessing Member State for an active substance used in multi-national clinical trials during the reporting period.



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 multi-national clinical trials since February 2022.


Austria 60
Belgium 125
Bulgaria 46
Croatia 16
Cyprus 2
Czechia 74
Denmark 96
Estonia 15
Finland 33
France 179
Germany 173
Greece 51
Hungary 72
Ireland 24
Italy 160
Latvia 11
Lithuania 14
Netherlands 129
Norway 43
Poland 120
Portugal 46
Romania 44
Slovakia 29
Slovenia 10
Spain 202
Sweden 66
0
50
100
150
200
250

Annex

Annex I - Information on Transitional Trials

Guidance and documents:

1. The European Commission Guidance for the transition of clinical trials as well as the Quick Guide on CTR.
2. CTIS: how to get started and how to transition a trial - collection of training and reference documents for new CTIS users.
3. The CTCG best practice guide and accompanying Annex I (cover letter template for sponsors with multinational trials) and Annex II (Fees for transitional trials in MSs). The guide aims to support sponsors transitioning multinational trials with protocols, IMPD or Investigator's Brochure that are not harmonised across Member States. The annex provides a template with information that should be provided in the cover letter of applications for transitioning a clinical trial authorised under the CTD to the CTR.
4. Chapter 5 of the CTIS Sponsor Handbook - it includes an overview of the transition period, general considerations for transitioning trials, the assessment timelines, and information on creating and managing trials transitioned to CTIS.
5. Module 23 of the CTIS online training programme - it includes instructions on how to submit a transitional trial, including submitting notifications and clinical trial results. An overview of the content is also available in the Quick Guide for Sponsors.

Past events:

1. The video recording and presentation of the CTIS Bitesize talk from 21 June 2023 on **how to submit a transitional trial in CTIS**, available on the event page;
2. The video recording of the CTIS webinar on 4 July 2023 on the **second year of transition**, available on the event page;
3. The video recording and presentations of the **Training** from 9 February 2024 **for non-commercial sponsors** on transitioning trials to the CTR and CTIS, available on the event page. This is of particular importance as it was organised specifically to support non-commercial sponsors and it also contains information on OMS and xEVMPD;
4. The video recording of the CTIS Bitesize talk from 29 February 2024, on **how to submit a transitional trial in CTIS**, available on the event page;
5. The video recording and presentations of the CTIS event from 25 March 2024, on **Clinical Trials Information System Webinar: Last Year of Transition**, available on the event page.

Annex II - 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).
Multi-national clinical trial		A clinical trial for which the sponsor submitted an application dossier to more than one Member State.
Mono-national 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 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.

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