



## Multistakeholder Platform event, 22 October 2024

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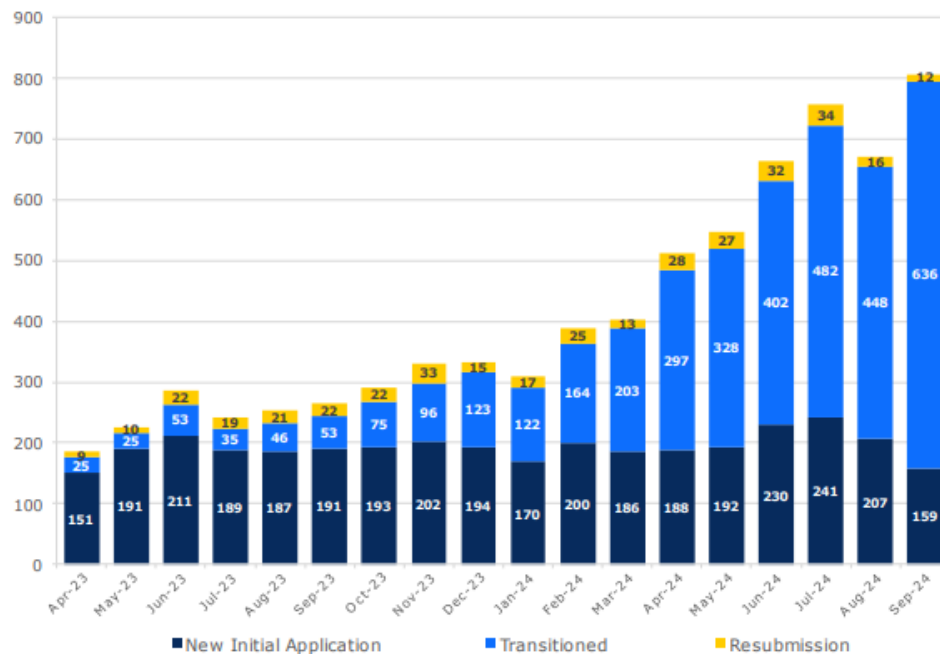
KPI on implementation of the CTR



- Priority Action 2 of ACT EU
- KPIs agreed within the Regulatory network
- To measure and monitor the European clinical trials environment
- First KPI report publication on 20 May 2022, under 'Implementation progress reports' tab
- Review of the KPI report in September 2023
- ANNEX on Information on Transitional Trials
- Glossary

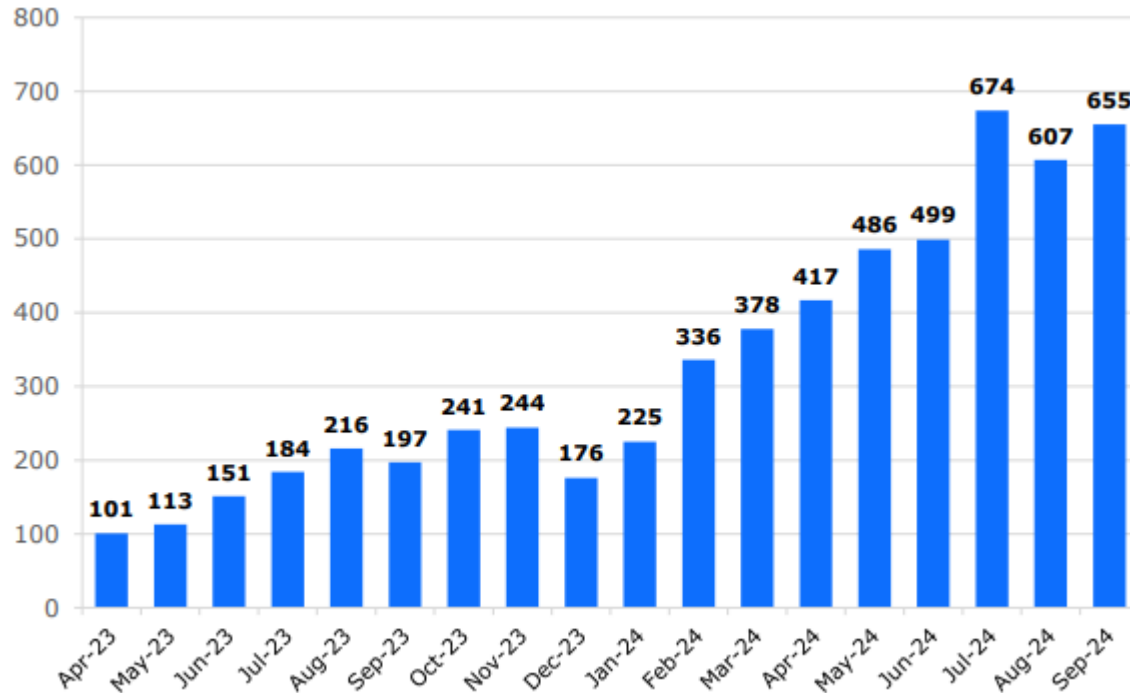


# Monthly submissions of initial clinical trial applications



- In September 2024, 807 initial CT applications have been submitted
- 8407 initial CT applications since 31 January 2022
- Upward trend of transitioning applications
- New initial CT applications are rather stable
- Resubmissions are stable

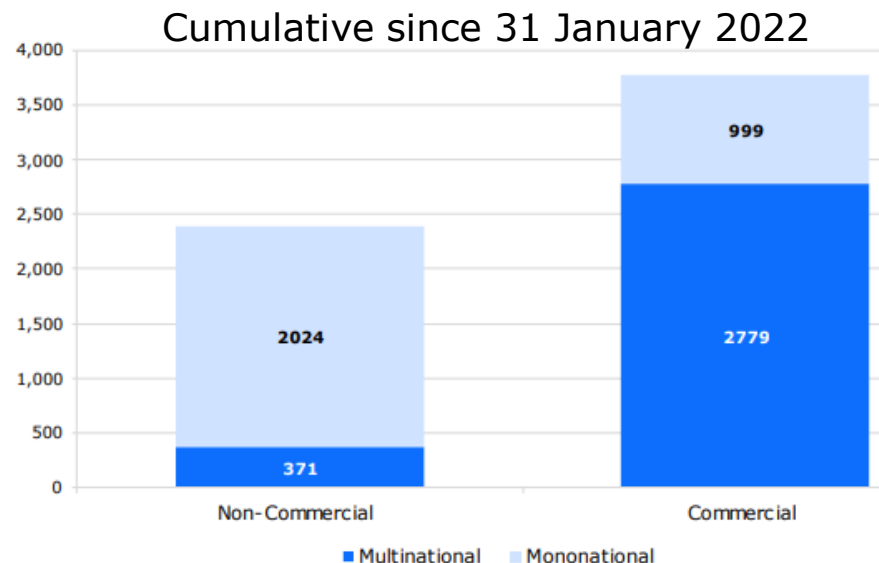
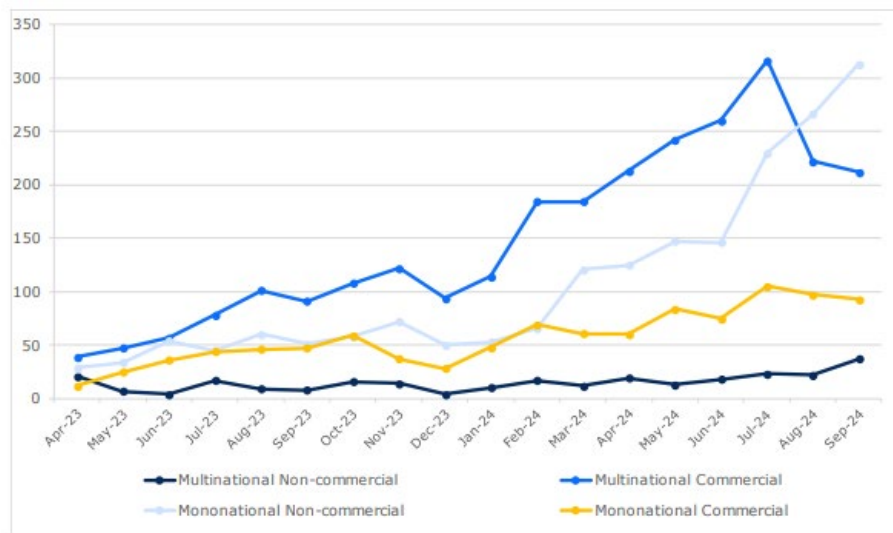
# Initial clinical trials with decision



In September 2024, 655 initial clinical trial applications received a decision, 650 have been authorised.

Figures include new initial applications, transitioning applications, and resubmissions.

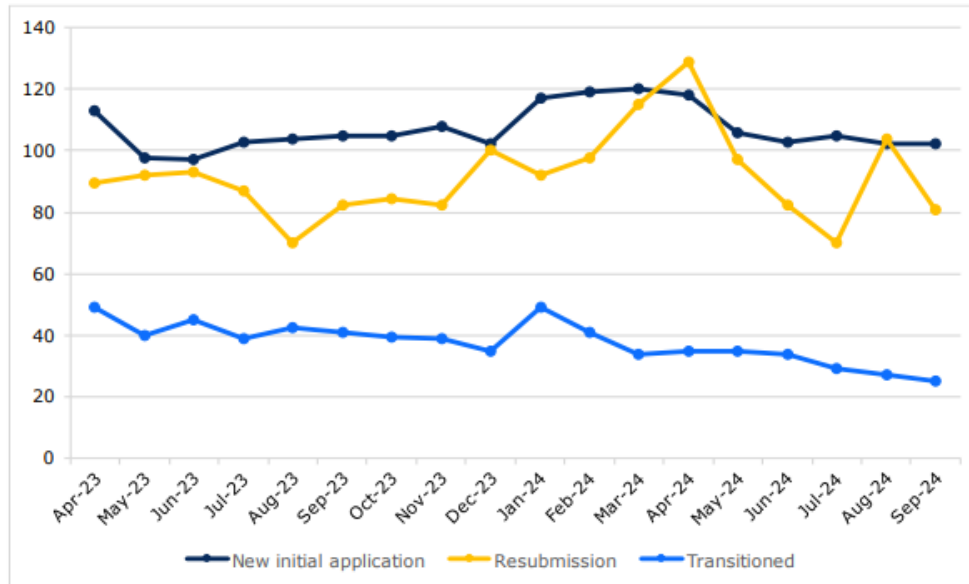
## Trials with a decision: commercial sponsors opt for multinational trials while non-commercial prefer mono-national trials



Support to non-commercial sponsors being addressed in a separate Priority Action.

# Median time from submission of initial clinical trial applications to decision

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



The time to decide on new applications is still too high (~106 days).

Progressively, less time to decide on transitioning applications. Great variety across countries.

Time to decide on resubmissions is quite high (~80 days).

# Distribution of submitted new initial clinical trial applications per Member State Concerned since 31 January 2022

Member State	Multinational Trials		Mononational Trials	Total number of Initial CTAs
	MSC	Of which as RMS		
Austria	279	46	33	312
Belgium	552	101	183	735
Bulgaria	280	3	17	297
Croatia	92	0	0	92
Cyprus	4	0	1	5
Czechia	417	81	36	453
Denmark	311	90	205	516
Estonia	52	4	5	57
Finland	123	33	31	154
France	961	154	390	1351
Germany	980	308	276	1256
Greece	262	2	13	275
Hungary	397	22	19	416
Iceland	7	0	1	8
Ireland	103	8	13	116
Italy	929	108	127	1056
Latvia	51	5	4	55
Lithuania	66	9	3	69
Luxembourg	2	0	1	3
Netherlands	471	105	301	772
Norway	132	21	41	173
Poland	759	77	65	824
Portugal	208	12	57	265
Romania	226	10	25	251
Slovakia	150	15	2	152
Slovenia	28	2	2	30
Spain	1208	351	293	1501
Sweden	242	57	90	332

## Mission

- For patients: Equal ratio of n. of clinical trials considering the population size
- For Member States: Equal chance to all Member States to be Reporting Member State
- For research: equal chance to have clinical trials in the country.

- To feed into the study on the implementation of the CTR expected to be published in Q1 2027 as per Article 97 of the Clinical Trials Regulation
- Review of the frequency of publications
- 3-year KPI report to be issued in Q1 2025
- Complementarity with other KPIs and measurements

