Medicines & Healthcare products Regulatory Agency

Performance Metrics

Assessment of Clinical Trial Authorisation Applications and Substantial Amendments

September 2022 – August 2023

Overview

We have provided metrics for clinical trials assessment performance, as follows.

- Average timelines for assessment of initial clinical trial authorisation (CTA) applications (by month) for Phase 1 healthy volunteer trials (HVT), initial CTA applications for Phase 1–4 patient trials, and substantial amendments. Since December 2021, applicants have had the flexibility to request additional time to respond to grounds for non-acceptance (GNA); therefore, the average assessment timeline for CTA applications has been divided into ‘first review’ (from receipt of valid application to first opinion letter) and ‘second review’ (from receipt of GNA response to final opinion letter). Before December 2021, applicants were required to respond to all GNA within 14 days.
- The number of CTA applications received and assessed by month.
- The number of substantial amendment applications received and assessed by month.
- The number of CTA applications assessed, by month, for the following trial categories: first in human; early phase (Phase 1/2); Phase 1 (healthy volunteers and patients); Phase 2 and 3; and Phase 4.
- The number of CTA applications assessed by sponsor type (non-commercial or commercial).
- The number of CTA applications and substantial amendments assessed, by month, for novel trials designs (e.g. umbrella, platform, modular, basket).

Summary of changes

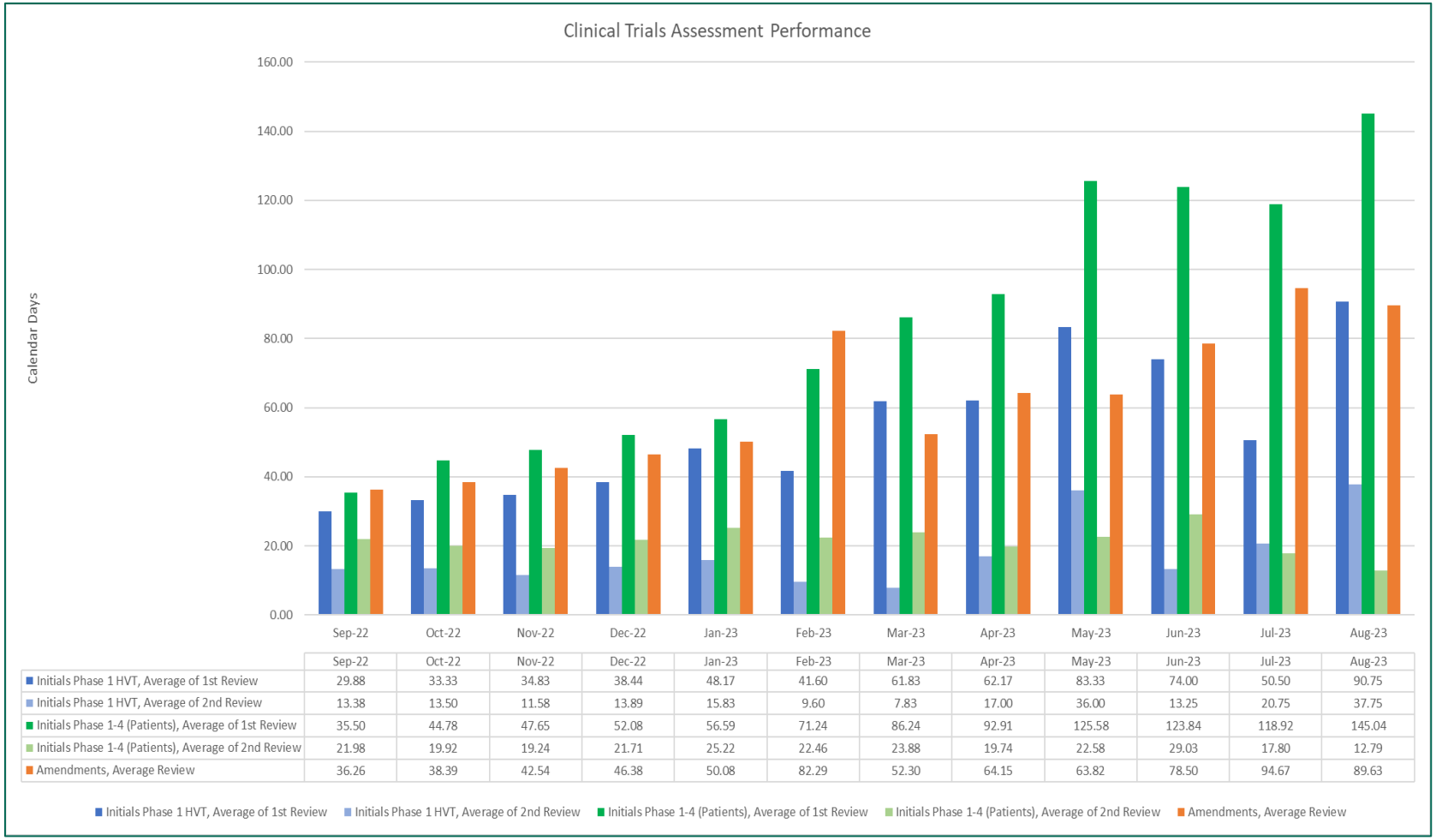
Number of applications

The number of initial CTA applications received in August 2023 decreased compared with July 2023 (from 74 to 66 applications), while the overall number of CTA applications assessed increased (320 compared with 38 applications). In August 2023, the number of substantial amendments received increased (from 436 to 517 amendments), with the number of amendments assessed also increasing (from 363 to 775 amendments) compared with July 2023.

Review times for clinical trials applications

Due to our substantial efforts to tackle the backlog throughout August 2023, the data on timeframes for this month is not meaningful or indicative of future performance. From next month we will be publishing new metrics and will be discussing these with our stakeholders to ensure they provide the most meaningful information. We are now completing regulatory assessments within statutory timeframes.

Figure 1. Average timeline (calendar days) for assessment of clinical trial applications: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued); initial CTA application second review (time from receipt of GNA response to final opinion); and substantial amendments

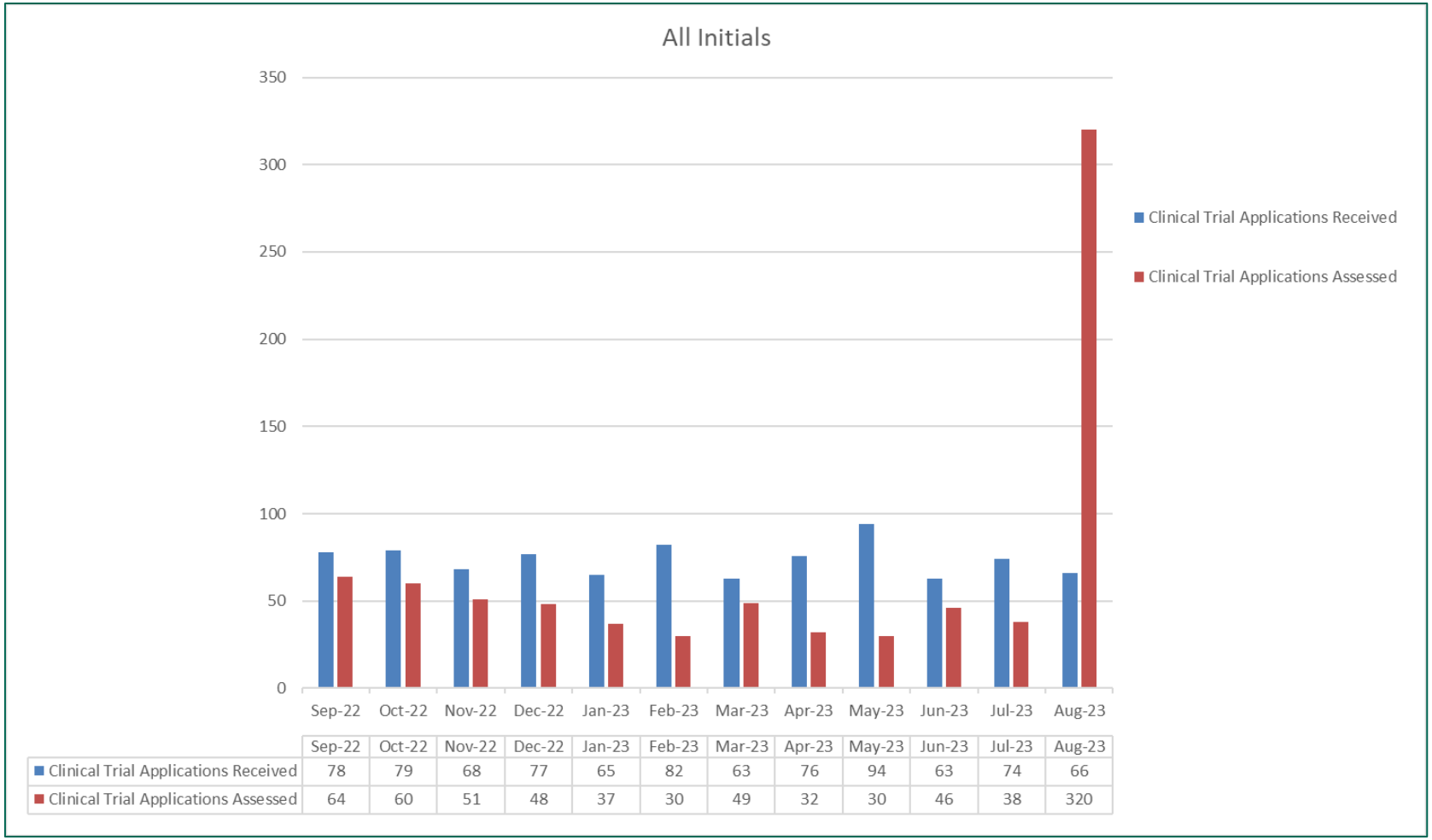


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Initials Phase 1 HVT, Average of 1st Review	29.88	33.33	34.83	38.44	48.17	41.60	61.83	62.17	83.33	74.00	50.50	90.75
Initials Phase 1 HVT, Average of 2nd Review	13.38	13.50	11.58	13.89	15.83	9.60	7.83	17.00	36.00	13.25	20.75	37.75
Initials Phase 1-4 (Patients), Average of 1st Review	35.50	44.78	47.65	52.08	56.59	71.24	86.24	92.91	125.58	123.84	118.92	145.04
Initials Phase 1-4 (Patients), Average of 2nd Review	21.98	19.92	19.24	21.71	25.22	22.46	23.88	19.74	22.58	29.03	17.80	12.79
Amendments, Average Review	36.26	38.39	42.54	46.38	50.08	82.29	52.30	64.15	63.82	78.50	94.67	89.63

Key features

Figure 1 shows the average time taken for MHRA assessment of clinical trial applications, divided into the following categories: initial clinical trial authorisation (CTA) applications for Phase 1 healthy volunteer trials (HVT); initial CTA applications for Phase 1–4 patient trials; and substantial amendments. Since December 2021, applicants have had the flexibility to request additional time to respond to grounds for non-acceptance (GNA); therefore, the data in Figure 1 are further categorised into: ‘first review’ – time from receipt of valid CTA application to initial opinion letter; and ‘second review’ – time from receipt of GNA response to final opinion. The monthly average for each category represents clinical trials for which the final opinion letter was issued in that month (ie outright approval, approval with conditions, or approval of amended request further to a GNA response).

Figure 2. Number of clinical trial authorisation (CTA) applications (‘initials’) received and assessed by month (September 2022–August 2023)

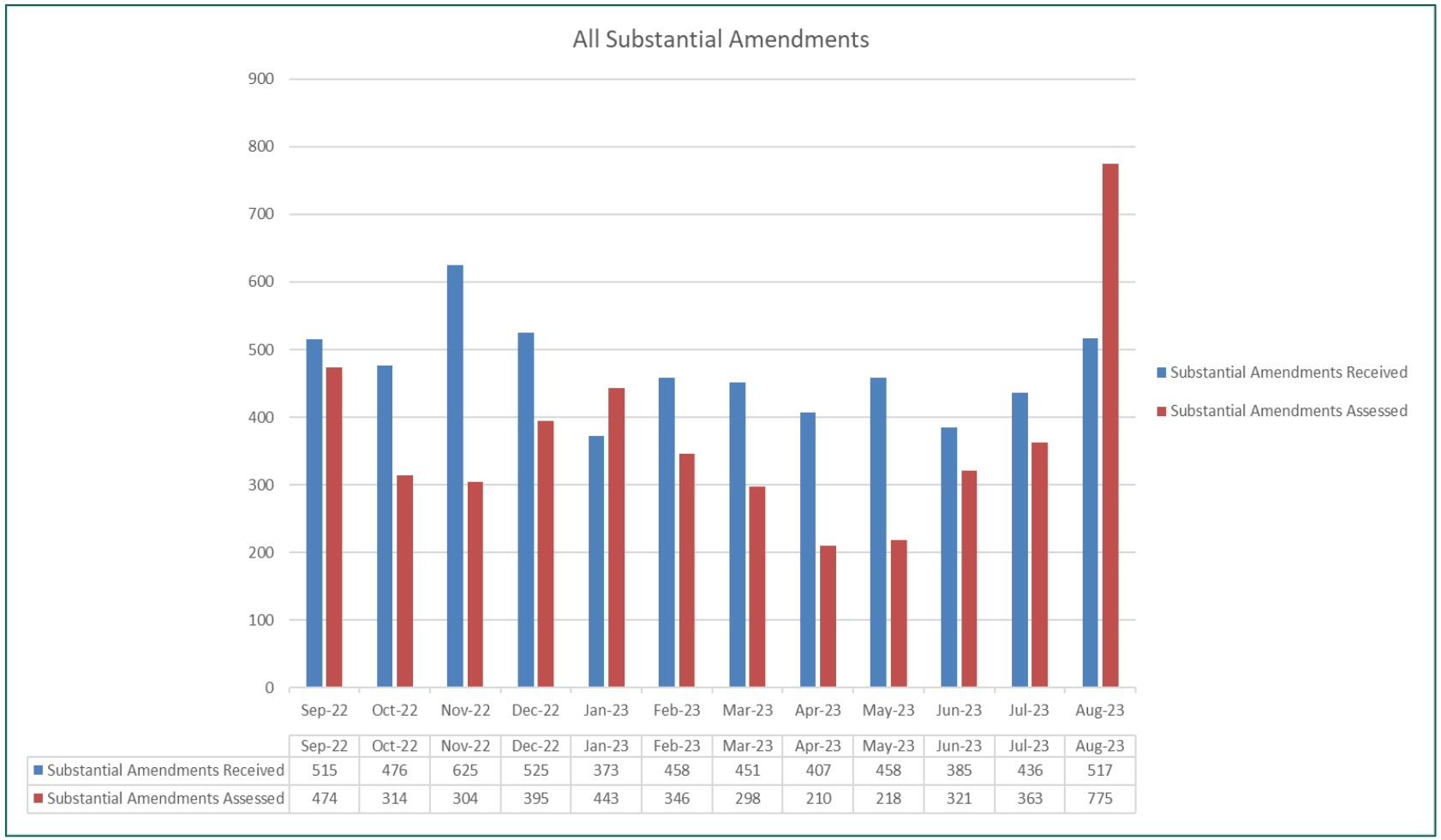


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Clinical Trial Applications Received	78	79	68	77	65	82	63	76	94	63	74	66
Clinical Trial Applications Assessed	64	60	51	48	37	30	49	32	30	46	38	320

Key features

Figure 2 shows the number of valid clinical trial authorisation (CTA) applications received and the number of CTA applications assessed in any given month. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

Figure 3. Number of substantial amendments received and assessed by month (September 2022–August 2023)

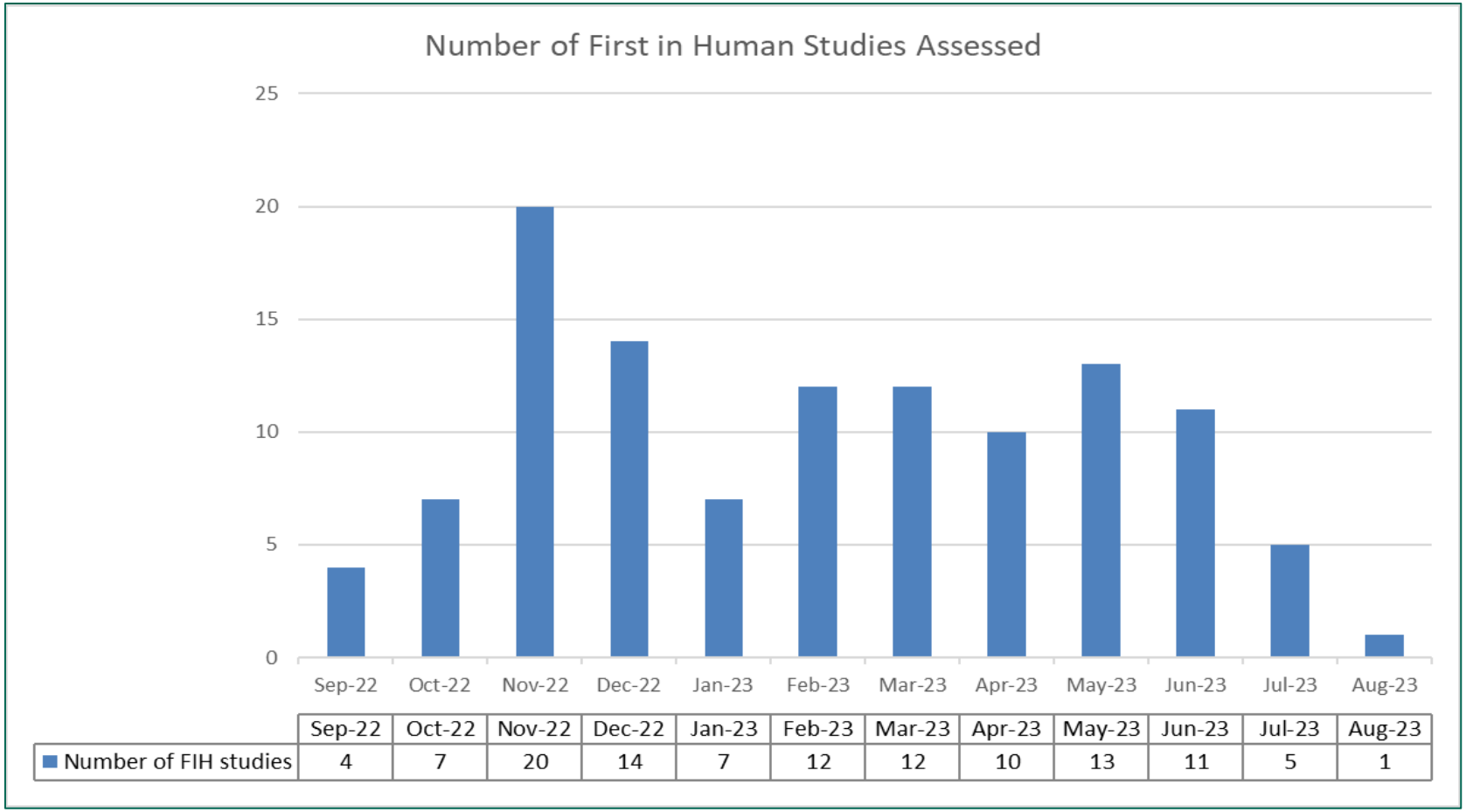


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Substantial Amendments Received	515	476	625	525	373	458	451	407	458	385	436	517
Substantial Amendments Assessed	474	314	304	395	443	346	298	210	218	321	363	775

Key features

Figure 3 shows the number of substantial amendments received and the number assessed in any given month. The number of amendments assessed for any given month is the number for which an opinion letter was issued in that month.

Figure 4. Number of first-in-human CTA applications assessed by month (September 2022–August 2023)



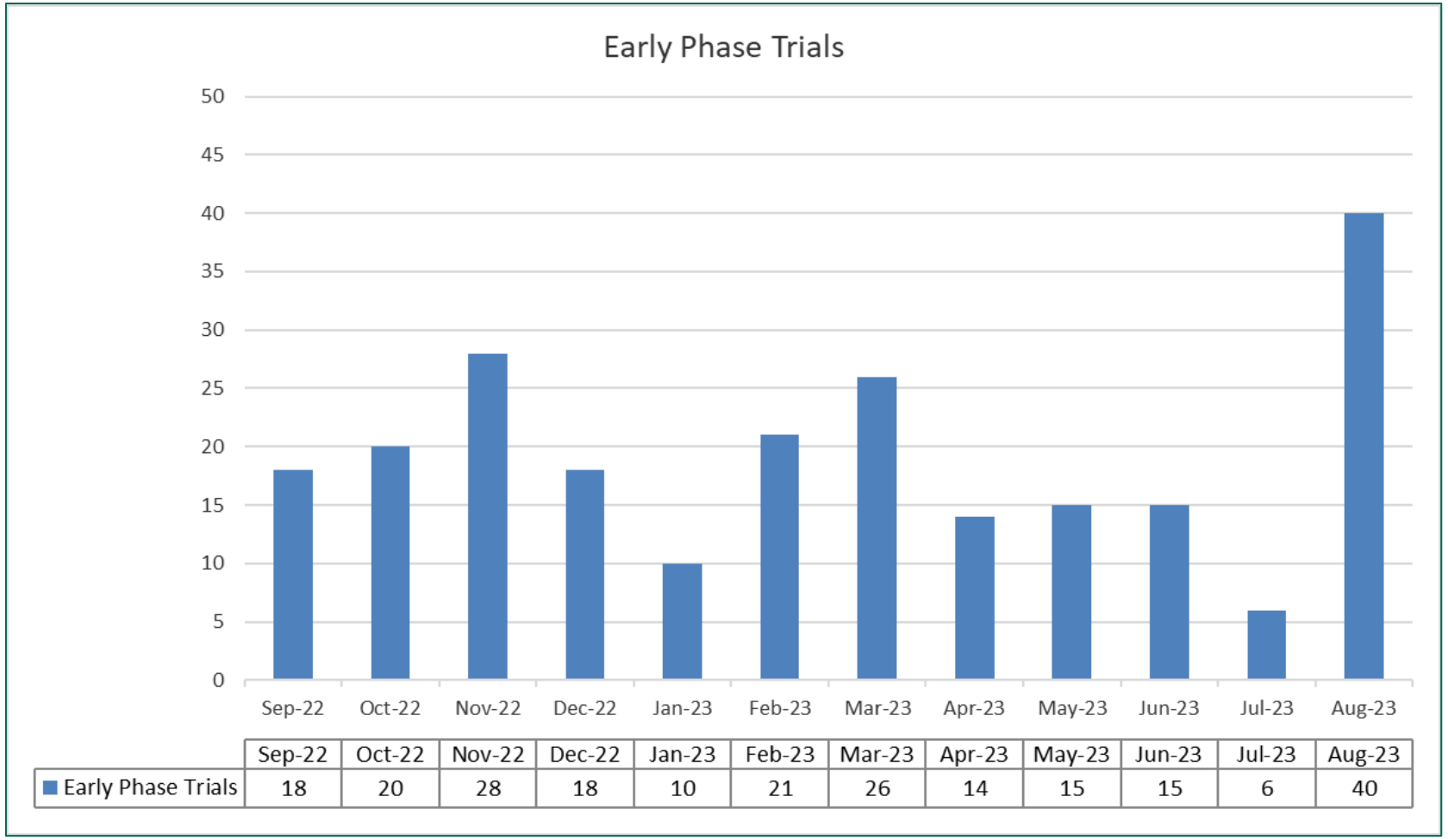
	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Number of FIH studies	4	7	20	14	7	12	12	10	13	11	5	1

Key features

Figure 4 shows the number of first-in-human clinical trial authorisation (CTA) applications assessed by month. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

(CTA = Clinical trial authorisation; FIH= First in Human)

Figure 5. Number of early phase CTA applications assessed by month (September 2022–August 2023)

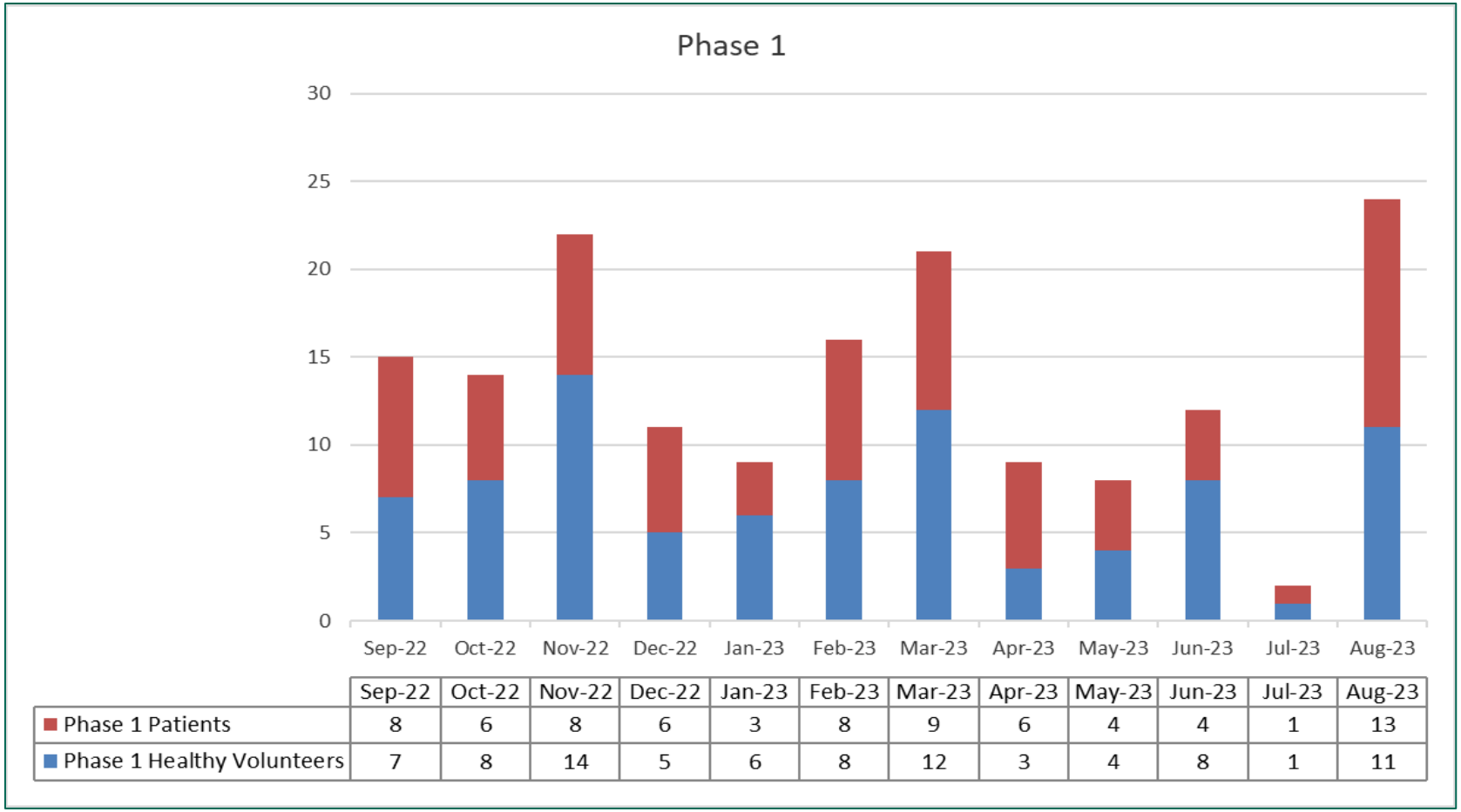


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Early Phase Trials	18	20	28	18	10	21	26	14	15	15	6	40

Key features

Figure 5 shows the number of clinical trial authorisation (CTA) applications assessed, by month, where the Sponsor has declared a Phase 1 element (e.g. Phase 1/2 trials). The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

Figure 6. Number of phase 1 CTA applications assessed by month (September 2022–August 2023)

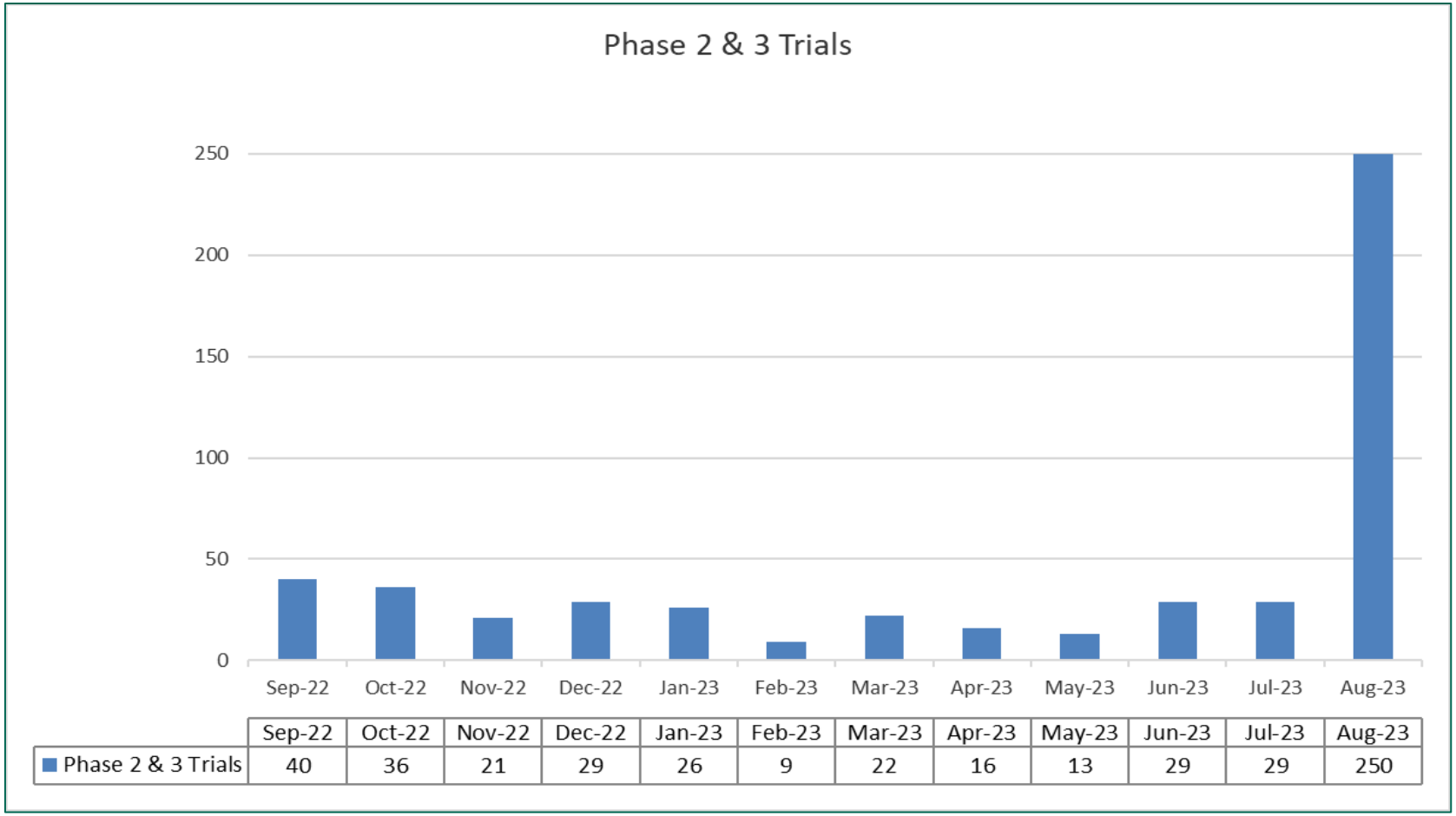


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 1 Patients	8	6	8	6	3	8	9	6	4	4	1	13
Phase 1 Healthy Volunteers	7	8	14	5	6	8	12	3	4	8	1	11

Key features

Figure 6 shows the number of Phase 1 clinical trial authorisation (CTA) applications assessed by month. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

Figure 7. Number of phase 2 and 3 CTA applications assessed by month (September 2022–August 2023)

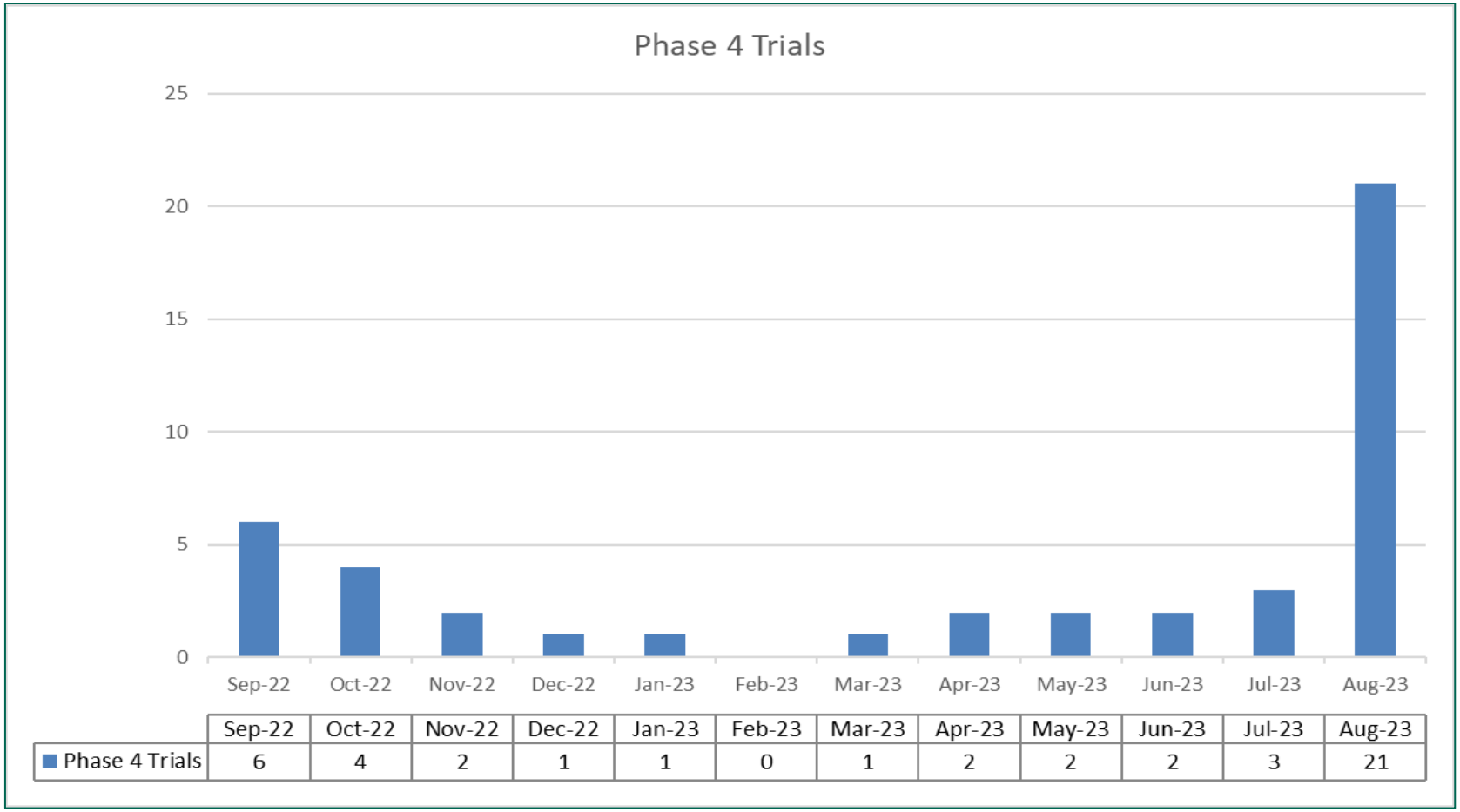


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 2 & 3 Trials	40	36	21	29	26	9	22	16	13	29	29	250

Key features

Figure 7 shows the number of clinical trial authorisation (CTA) applications assessed, by month, where the Sponsor has declared a Phase 2 or 3 element. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

Figure 8. Number of phase 4 CTA applications assessed by month (September 2022– August 2023)

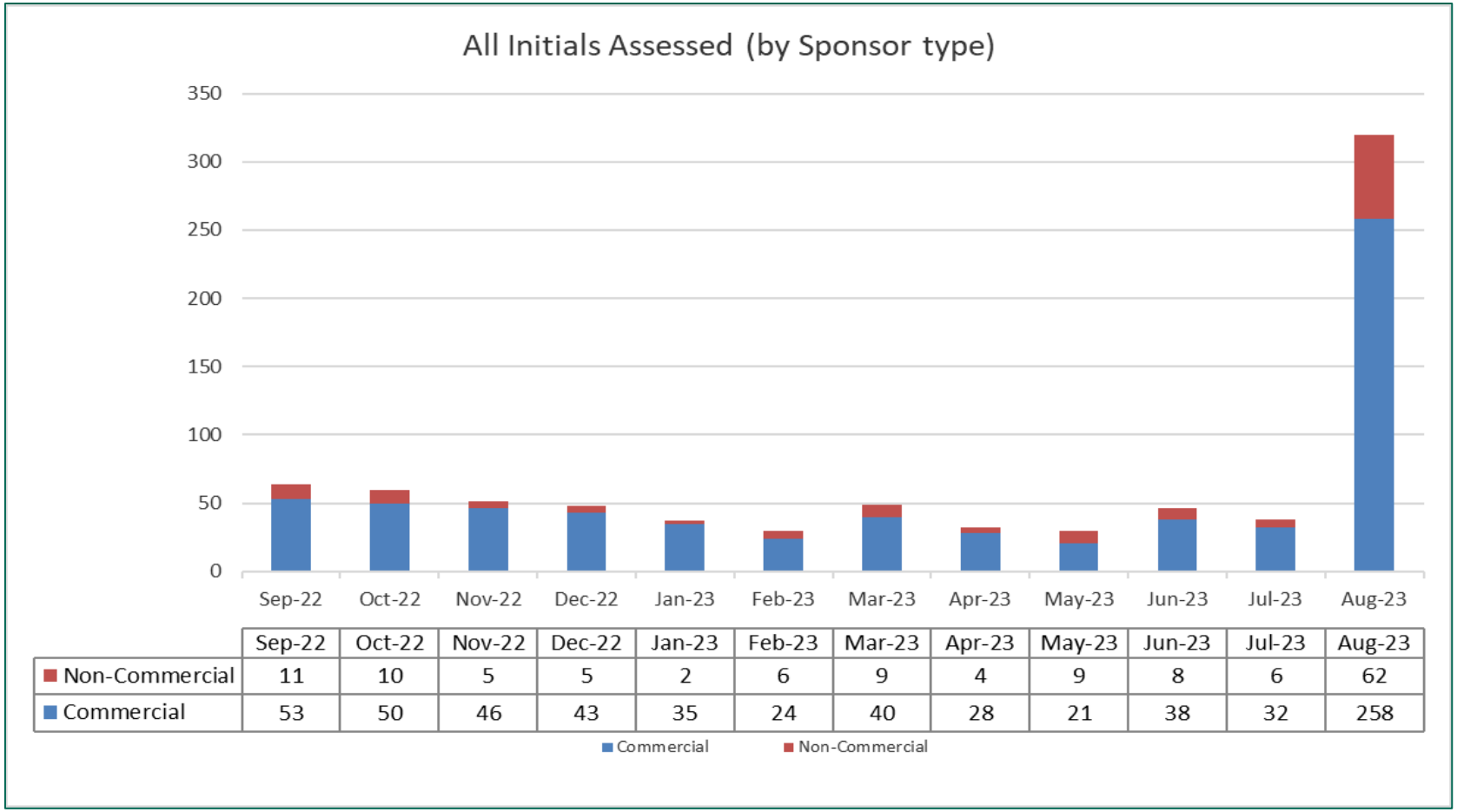


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 4 Trials	6	4	2	1	1	0	1	2	2	2	3	21

Key features

Figure 8 shows the number of clinical trial authorisation (CTA) applications assessed, by month, where the Sponsor has declared the trial to be Phase 4. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review).

Figure 9. Number of clinical trial authorisation (CTA) applications (‘initials’) assessed by sponsor type by month (September 2022–August 2023)

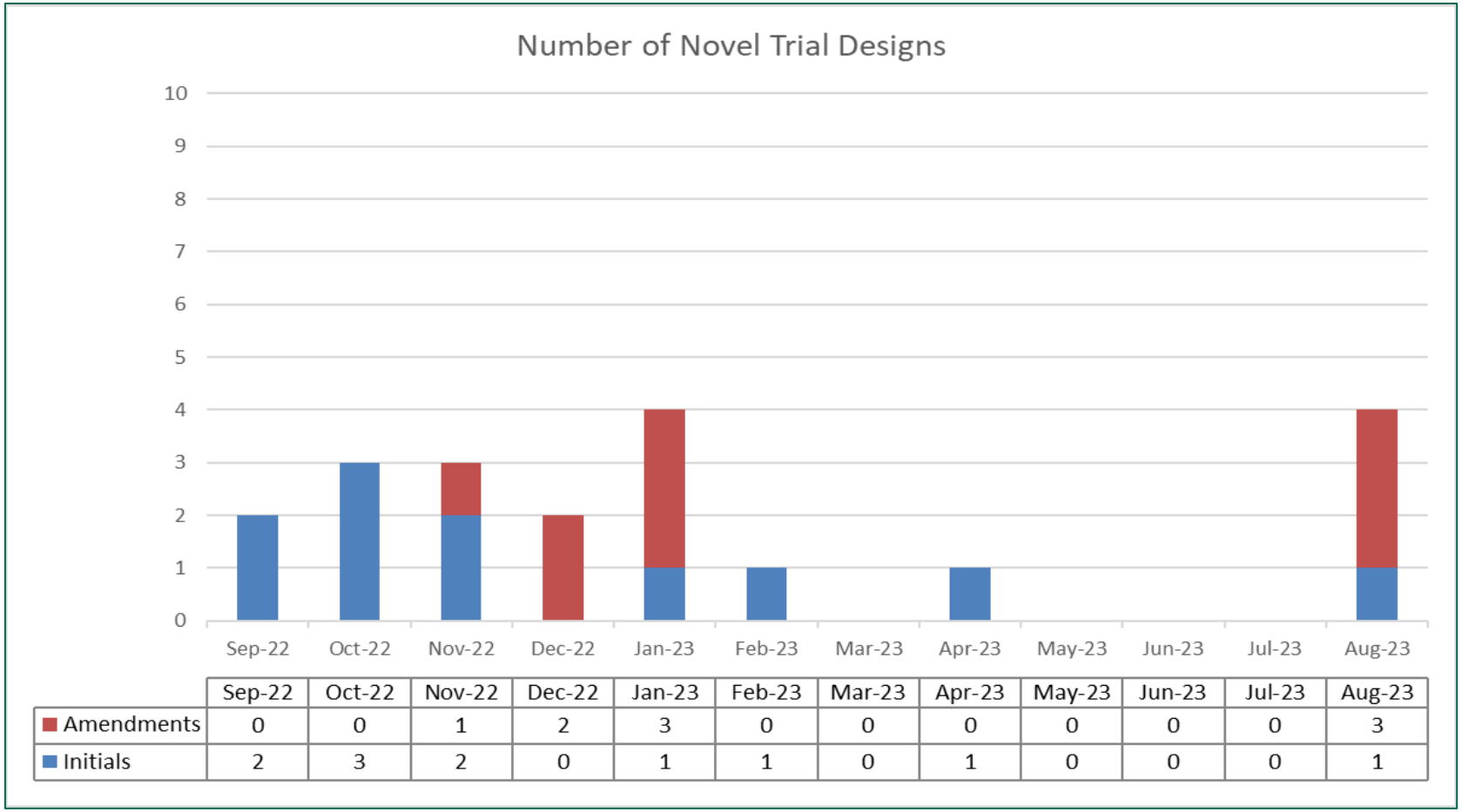


	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Non-Commercial	11	10	5	5	2	6	9	4	9	8	6	62
Commercial	53	50	46	43	35	24	40	28	21	38	32	258

Key features

Figure 9 shows the number of clinical trial authorisation (CTA) applications assessed in any given month, spit by commercial and non-commercial sponsors. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (ie first review)

Figure 10. Number of novel trial designs assessed by month: initial clinical trial authorisation (CTA) applications and amendments (September 2022–August 2023)



	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Amendments	0	0	1	2	3	0	0	0	0	0	0	3
Initials	2	3	2	0	1	1	0	1	0	0	0	1

Key features

Figure 10 shows the number of clinical trial authorisation (CTA) applications ('initials') and the number of substantial amendments assessed for novel trial designs (eg umbrella, platform, modular, basket) by month. The data for initials assessed in any given month represent the number of CTA applications for which the first opinion letter was issued in that month. Figure 10 does not show the number of applications received.

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