Medicines & Healthcare products Regulatory Agency

Performance Metrics

Assessment of Clinical Trial Authorisation Applications and Substantial Amendments

August 2022 – July 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

Review times for clinical trials applications

In July 2023, the average times for MHRA assessment of clinical trials applications were as follows:

- For an initial clinical trial authorisation (CTA) application, divided into ‘first review’ (time from receipt of valid application to initial opinion letter) and ‘second review’ (the time from receipt of GNA response to final opinion) the average time was:
  - 50.50 and 20.75 days, respectively, for Phase 1 healthy volunteer trials; and
  - 118.92 and 17.80 days, respectively, for Phase 1–4 patient trials.
- The average time for assessment of a substantial amendment was 94.67 days.

Number of applications and assessments

The number of initial CTA applications received in July 2023 increased compared with June 2023 (from 63 to 74 applications)

The number of initial clinical trial applications assessed by MHRA were 38

The number of substantial amendments received increased (from 385 to 436 amendments)

The number of substantial clinical trial amendments assessed by MHRA were 363

Additional data for 31 July – 11 August

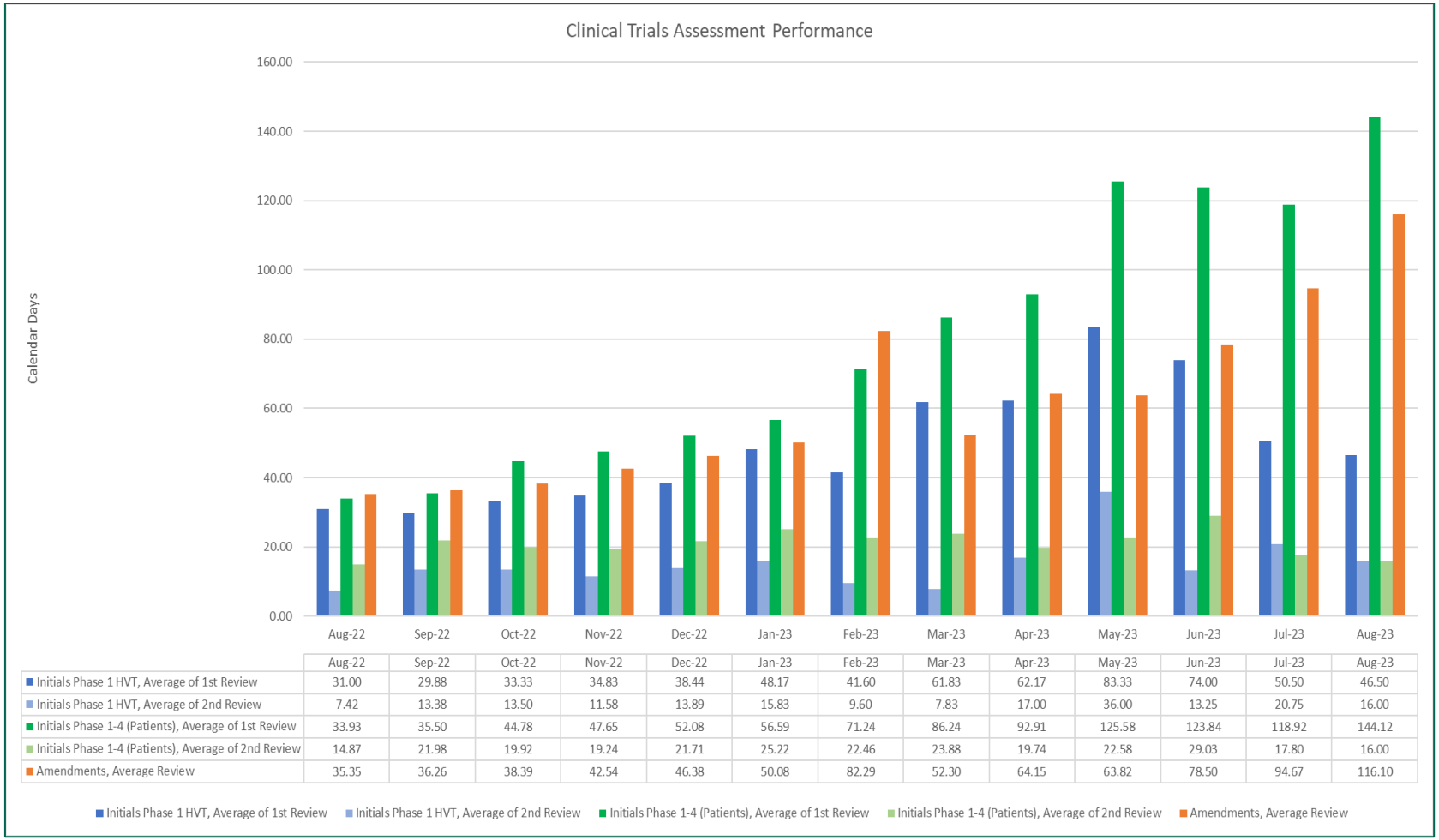
The MHRA is committed to providing clinical trials applicants with as much information as possible in order to provide more certainty about when regulatory applications will be determined; and to demonstrate the impact of interventions we have put in place to eliminate backlogs.

We are therefore providing additional summary data relating to total applications assessed between 31 July – 11 August 2023.

- The number of initial clinical trial applications assessed by MHRA were 116
- The number of substantial clinical trial amendments assessed by MHRA were 231

We will update this data fortnightly to provide greater predictability in our assessment timescales.

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

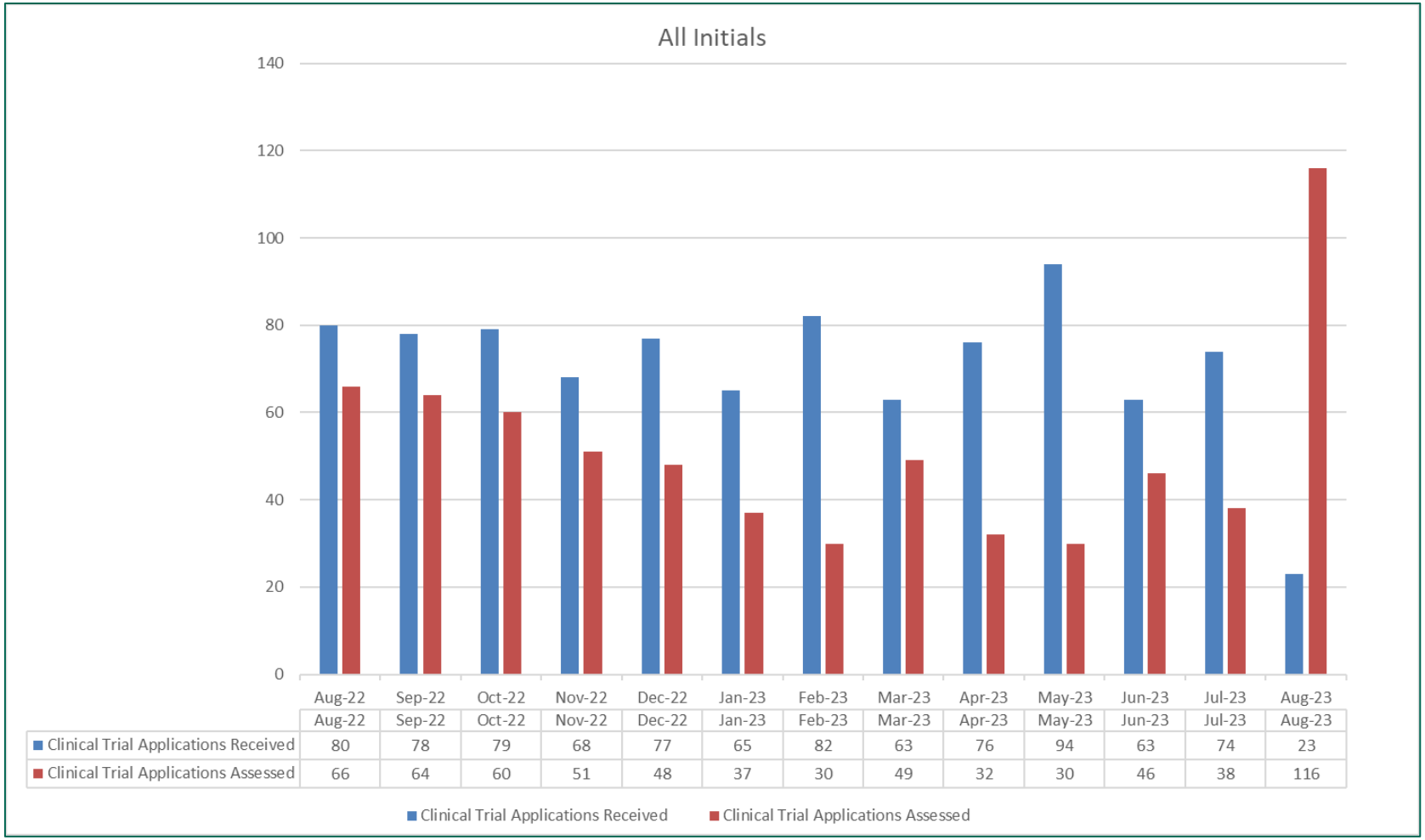


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Initials Phase 1 HVT, Average of 1st Review	31.00	29.88	33.33	34.83	38.44	48.17	41.60	61.83	62.17	83.33	74.00	50.50	46.50
Initials Phase 1 HVT, Average of 2nd Review	7.42	13.38	13.50	11.58	13.89	15.83	9.60	7.83	17.00	36.00	13.25	20.75	16.00
Initials Phase 1-4 (Patients), Average of 1st Review	33.93	35.50	44.78	47.65	52.08	56.59	71.24	86.24	92.91	125.58	123.84	118.92	144.12
Initials Phase 1-4 (Patients), Average of 2nd Review	14.87	21.98	19.92	19.24	21.71	25.22	22.46	23.88	19.74	22.58	29.03	17.80	16.00
Amendments, Average Review	35.35	36.26	38.39	42.54	46.38	50.08	82.29	52.30	64.15	63.82	78.50	94.67	116.10

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 (August 2022–Jul/Aug 2023)

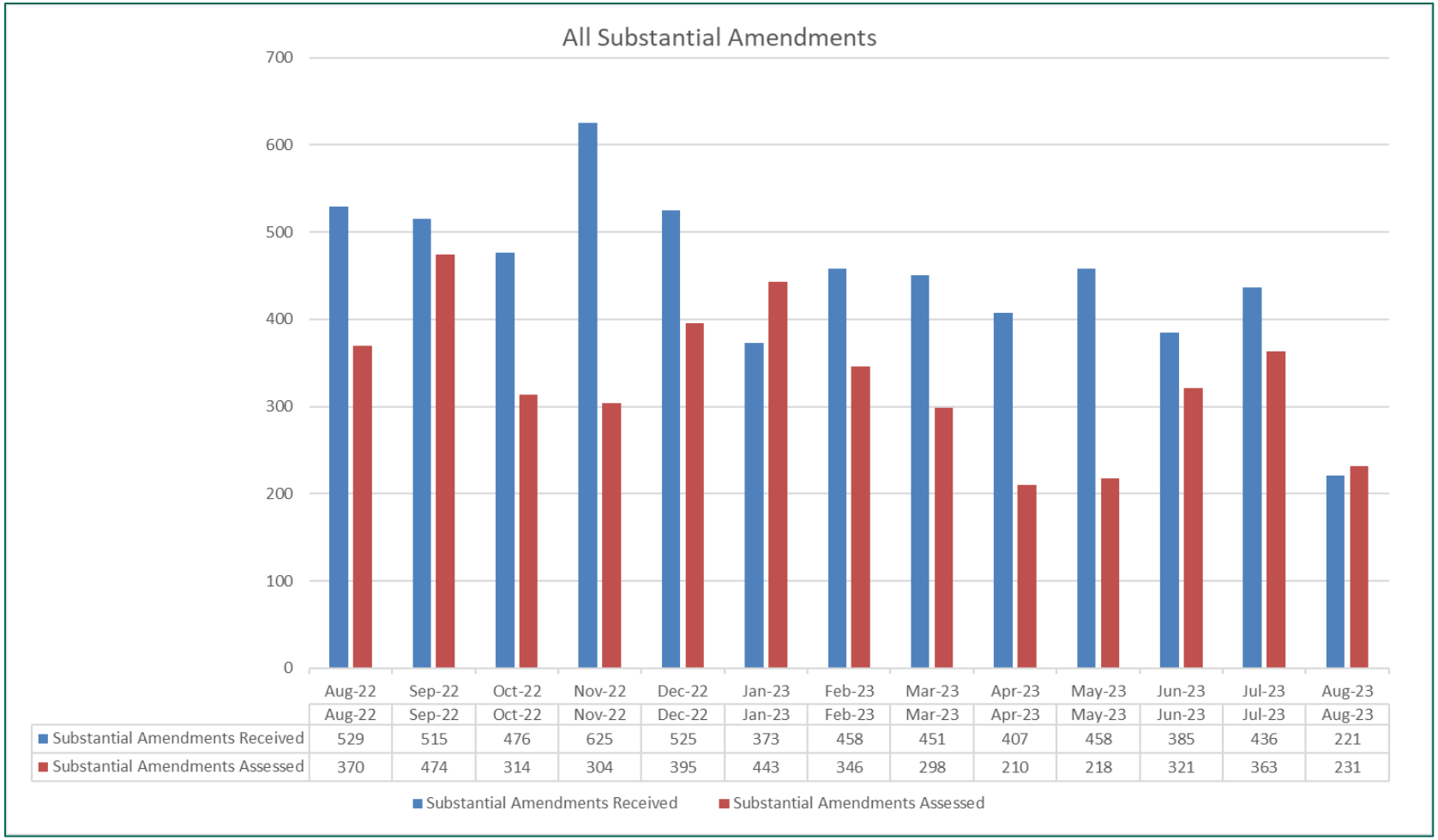


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Clinical Trial Applications Received	80	78	79	68	77	65	82	63	76	94	63	74	23
Clinical Trial Applications Assessed	66	64	60	51	48	37	30	49	32	30	46	38	116

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 (August 2022–Jul/Aug 2023)

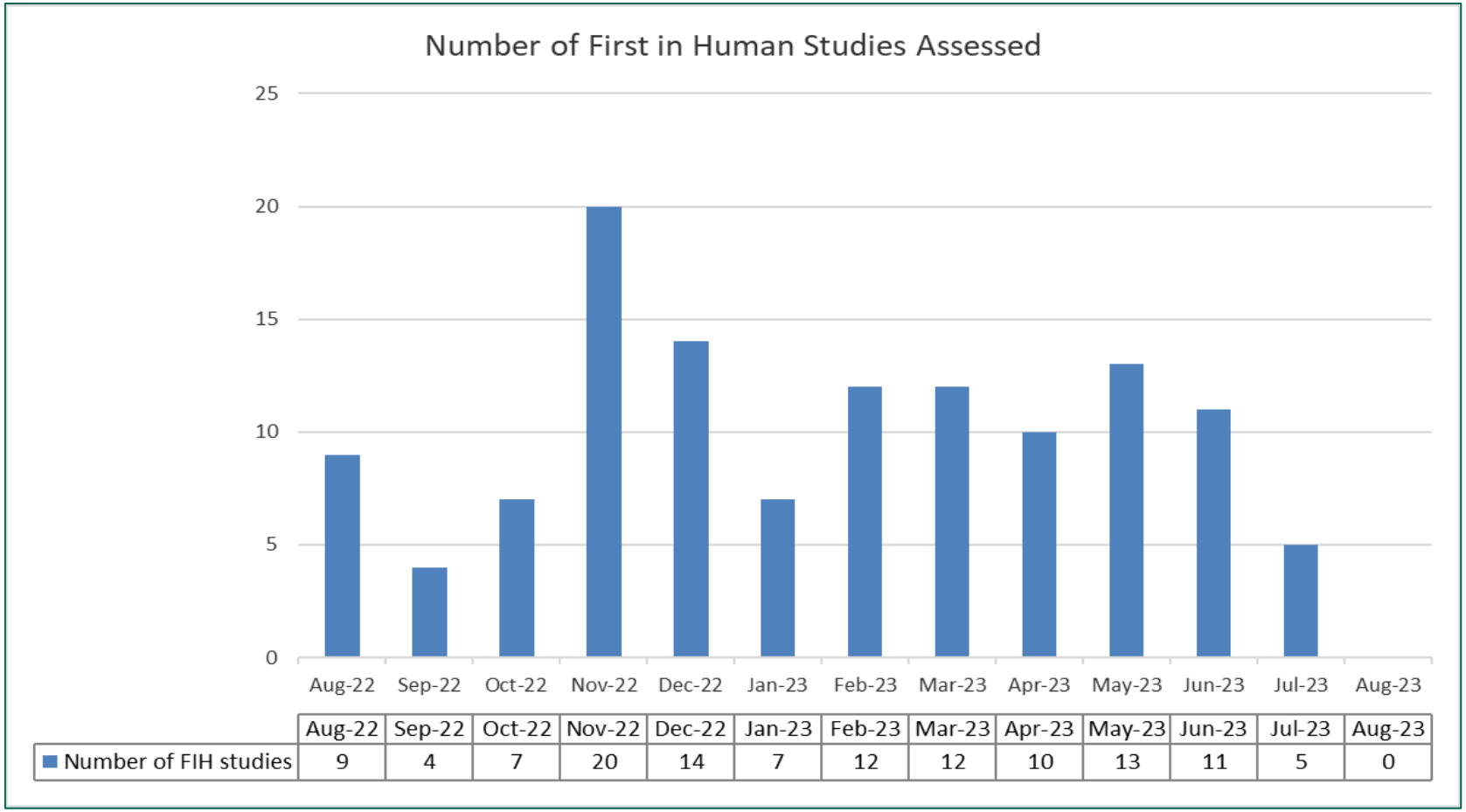


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Substantial Amendments Received	529	515	476	625	525	373	458	451	407	458	385	436	221
Substantial Amendments Assessed	370	474	314	304	395	443	346	298	210	218	321	363	231

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 (August 2022–Jul/Aug 2023)

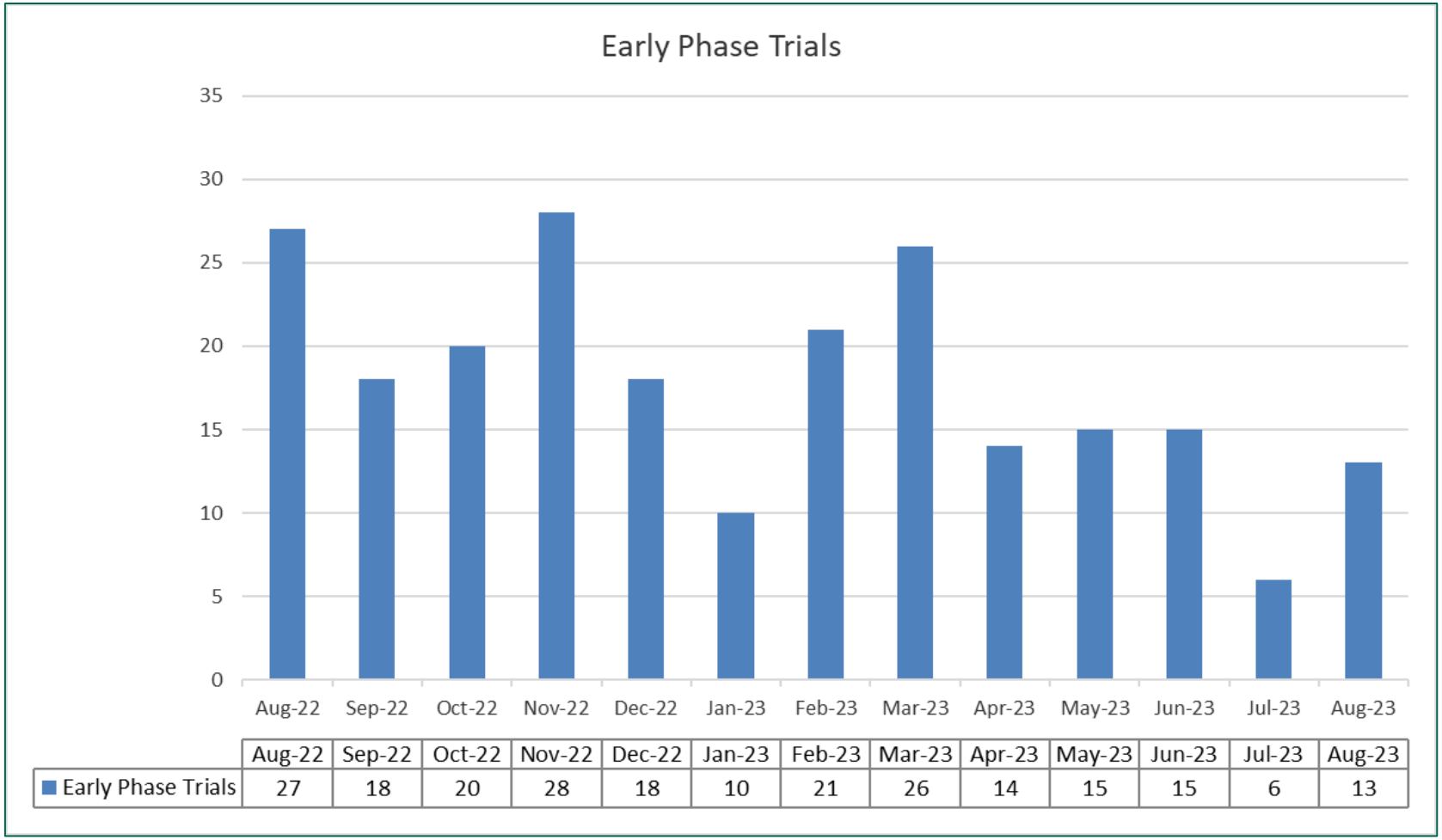


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Number of FIH studies	9	4	7	20	14	7	12	12	10	13	11	5	0

Key features

Figure 4 shows the number of first-in-human CTAs 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 5. Number of early phase CTA applications assessed by month (August 2022– Jul/Aug 2023)

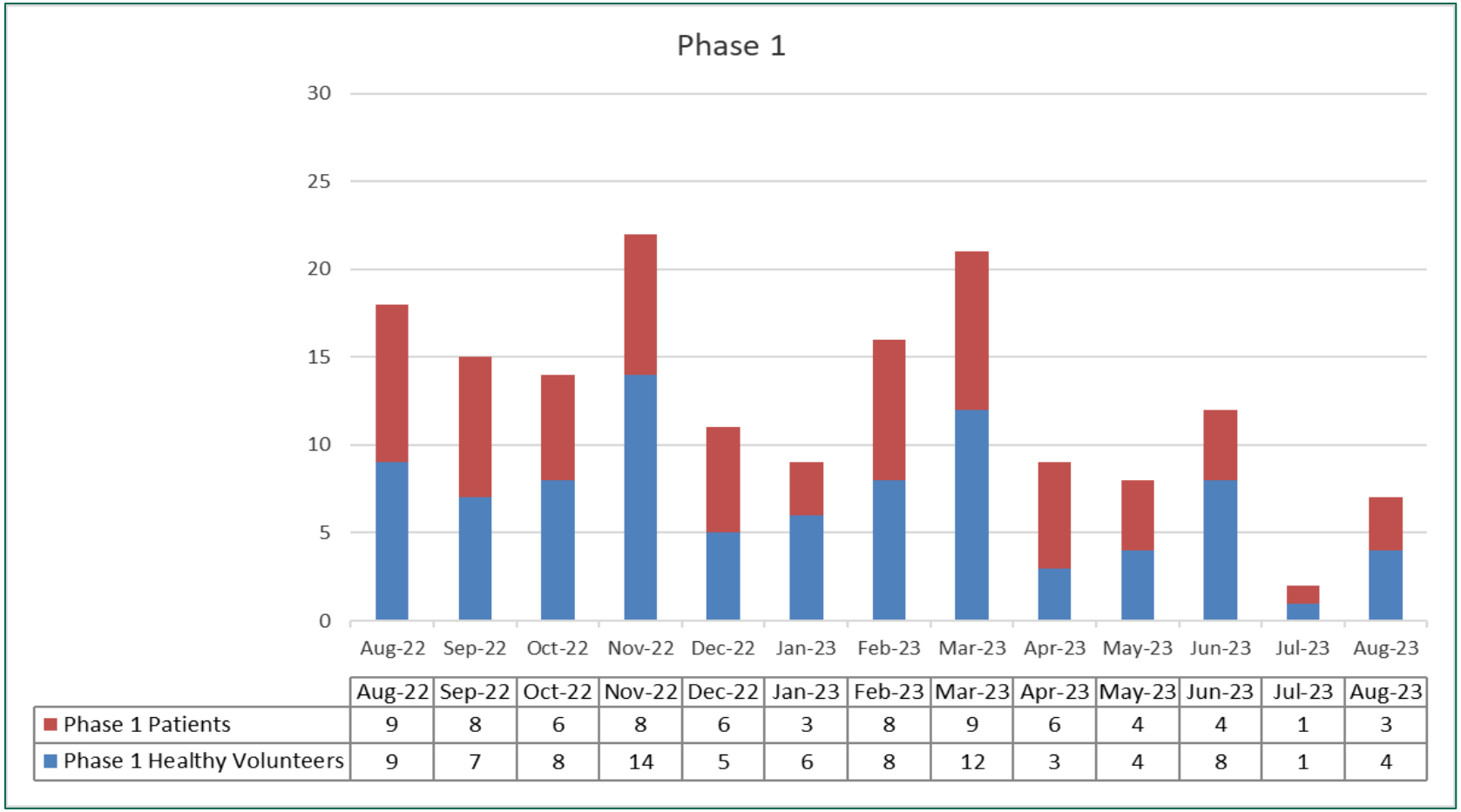


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Early Phase Trials	27	18	20	28	18	10	21	26	14	15	15	6	13

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 (August 2022–Jul/Aug 2023)

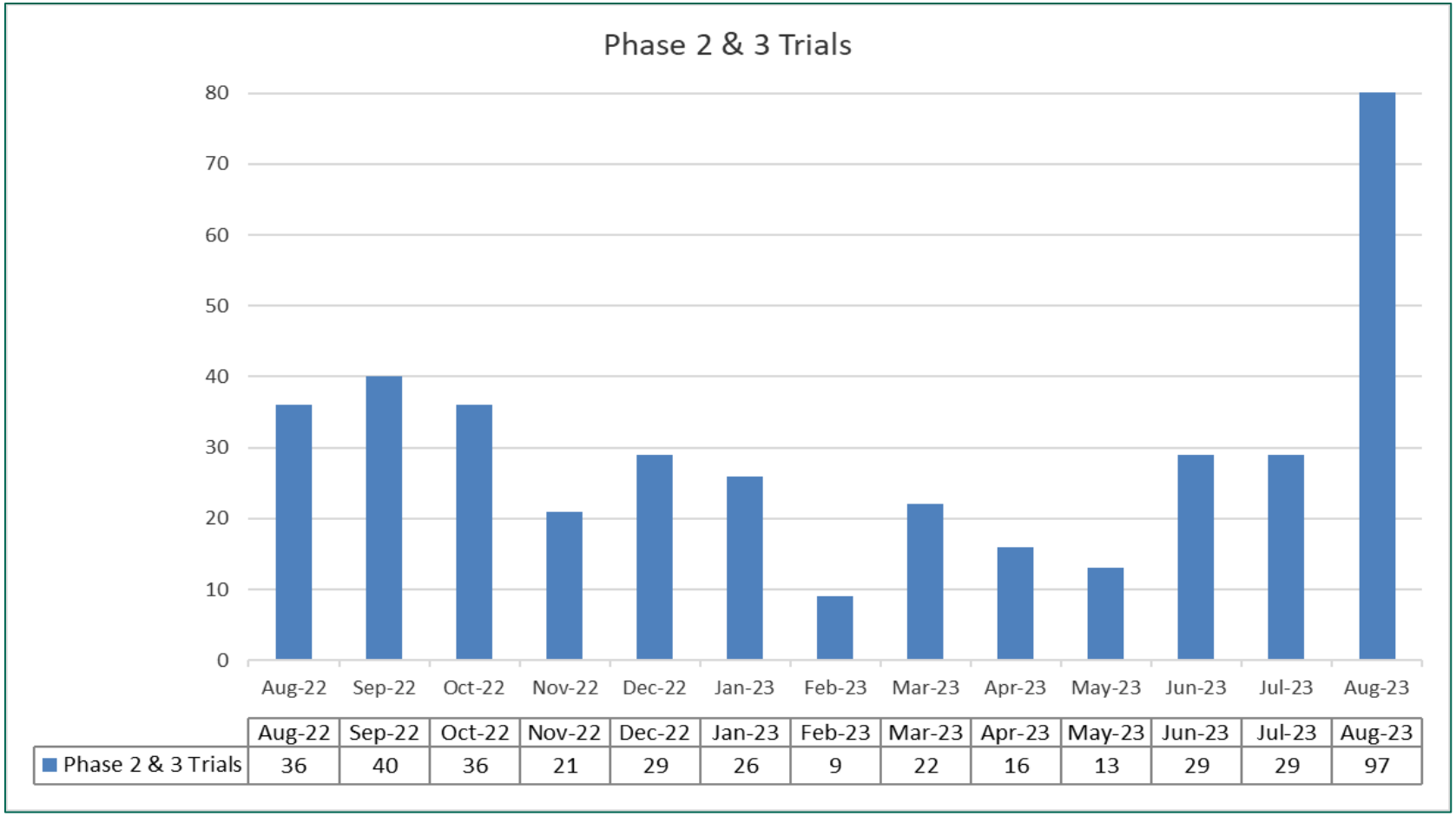


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 1 Patients	9	8	6	8	6	3	8	9	6	4	4	1	3
Phase 1 Healthy Volunteers	9	7	8	14	5	6	8	12	3	4	8	1	4

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 (August 2022–Jul/Aug 2023)

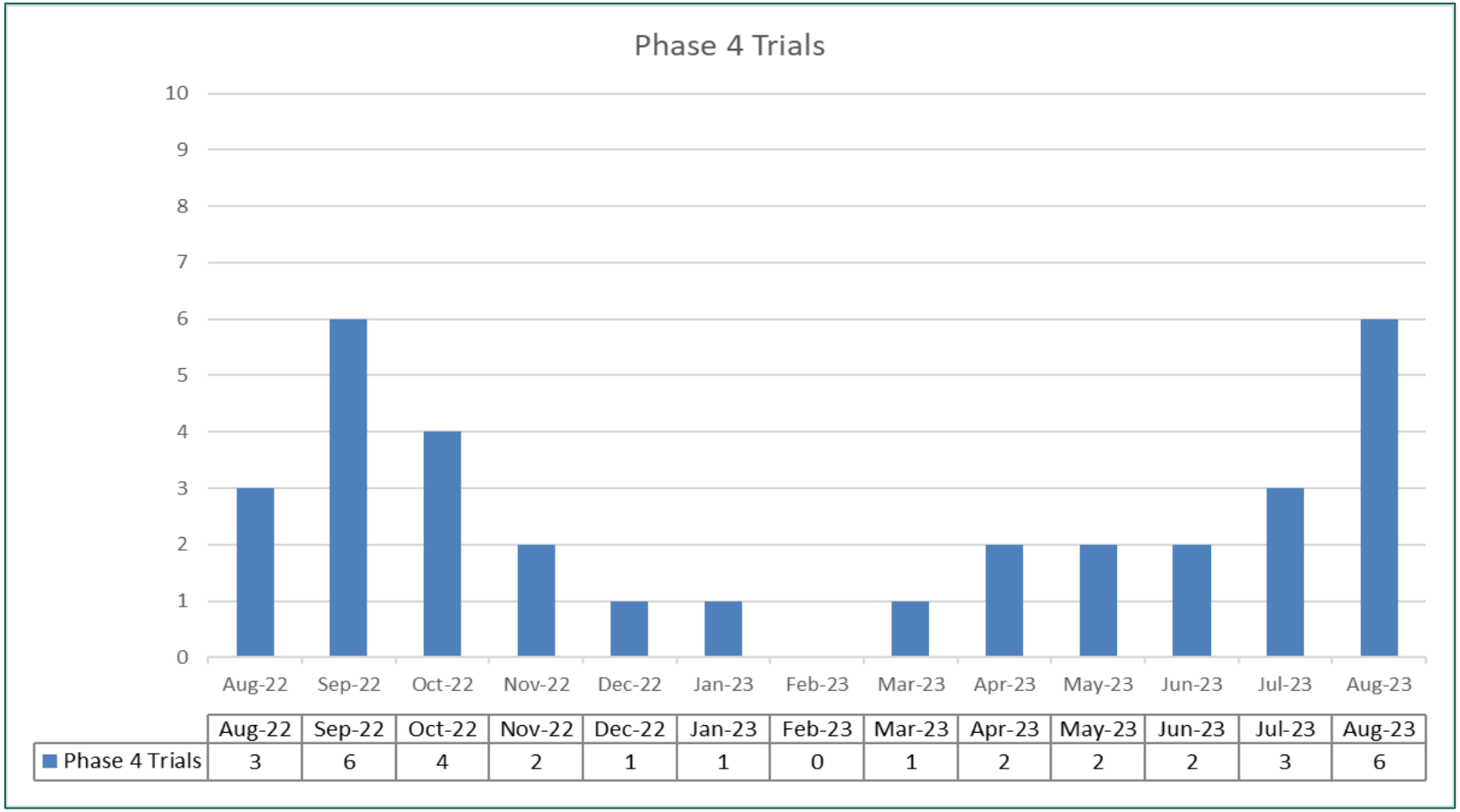


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 2 & 3 Trials	36	40	36	21	29	26	9	22	16	13	29	29	97

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 (August 2022–Jul/Aug 2023)

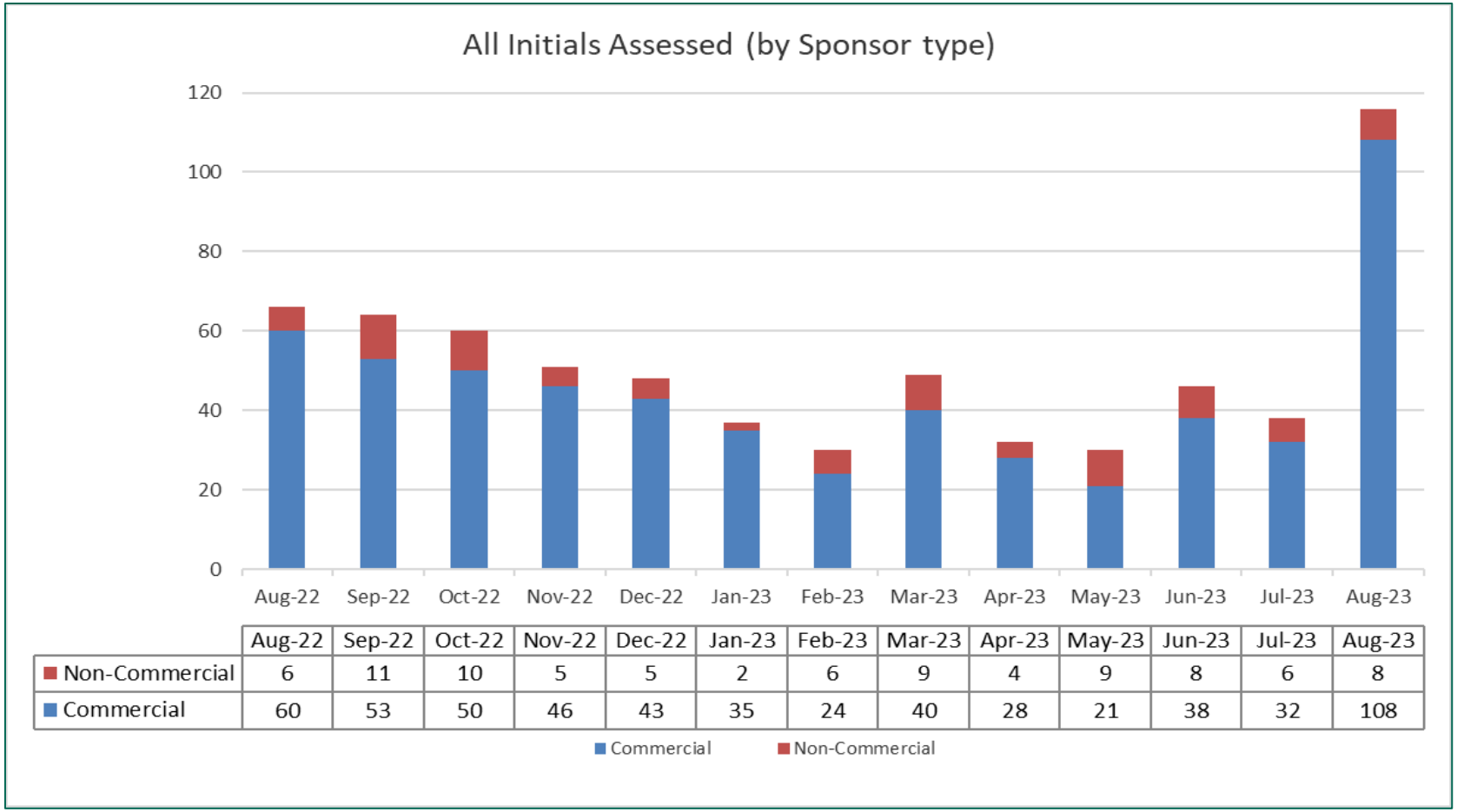


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Phase 4 Trials	3	6	4	2	1	1	0	1	2	2	2	3	6

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 (August 2022–July 2023)

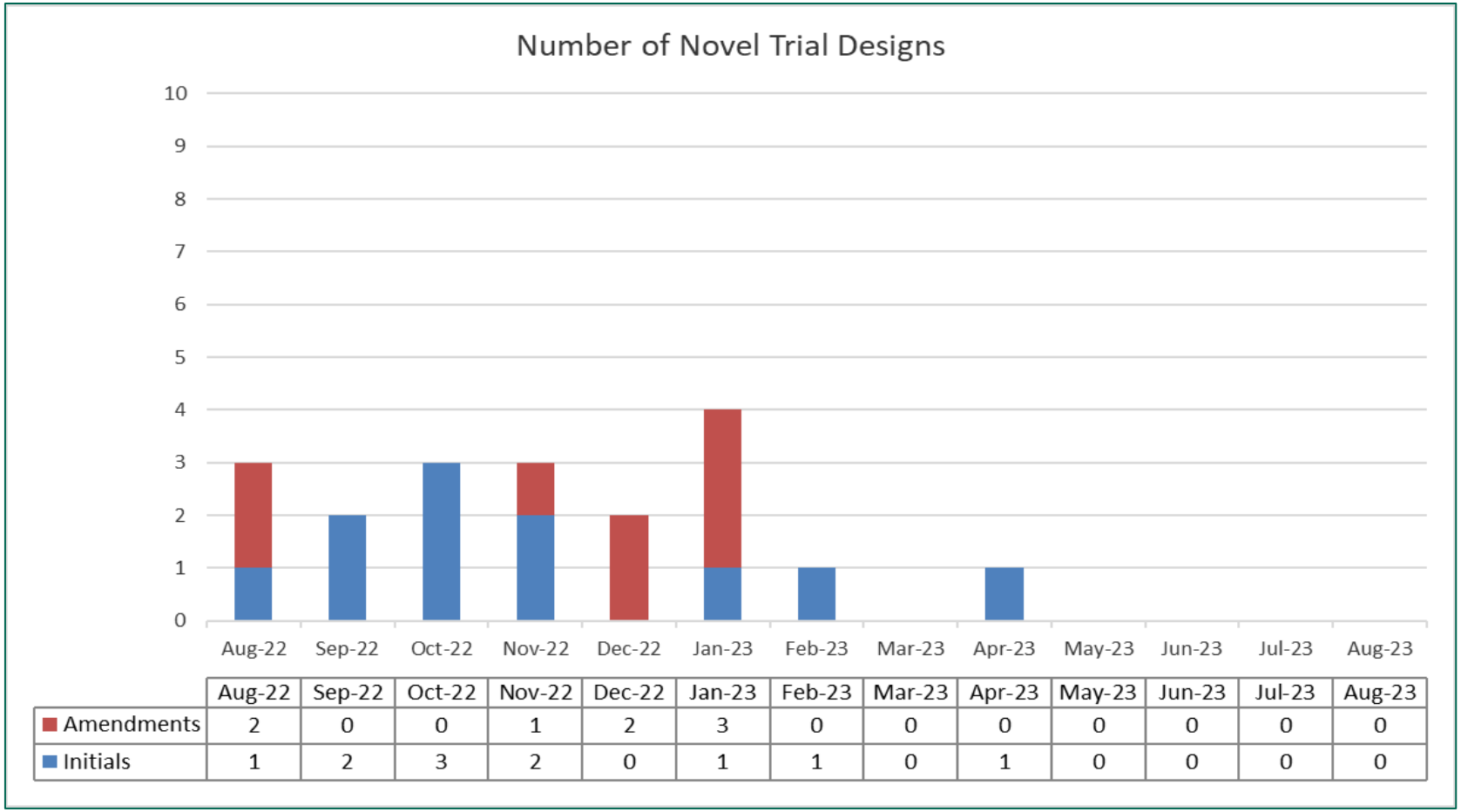


	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Non-Commercial	6	11	10	5	5	2	6	9	4	9	8	6	8
Commercial	60	53	50	46	43	35	24	40	28	21	38	32	108

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 (August 2022–Jul/Aug 2023)



	Aug-22	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	2	0	0	1	2	3	0	0	0	0	0	0	0
Initials	1	2	3	2	0	1	1	0	1	0	0	0	0

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.

Copyright information