



Medicines & Healthcare products
Regulatory Agency

Performance Metrics

Assessment of Clinical Trial
Authorisation Applications and
Substantial Amendments

October 2022 – September 2023



Overview

Explanation of the metrics provided

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 for applications submitted before 1 September 2023 (Figure 1) and those submitted from 1 September 2023 onwards (Figure 2). 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

Changes compare with the previous month

Summary of changes

Review times for clinical trials applications

Due to our continued efforts to tackle any remaining backlogged applications in September, we have split data on timeframes for applications submitted before 1 September 2023 and those submitted from 1 September 2023. Statutory timeframes are being met for all applications submitted after 1 September 2023.

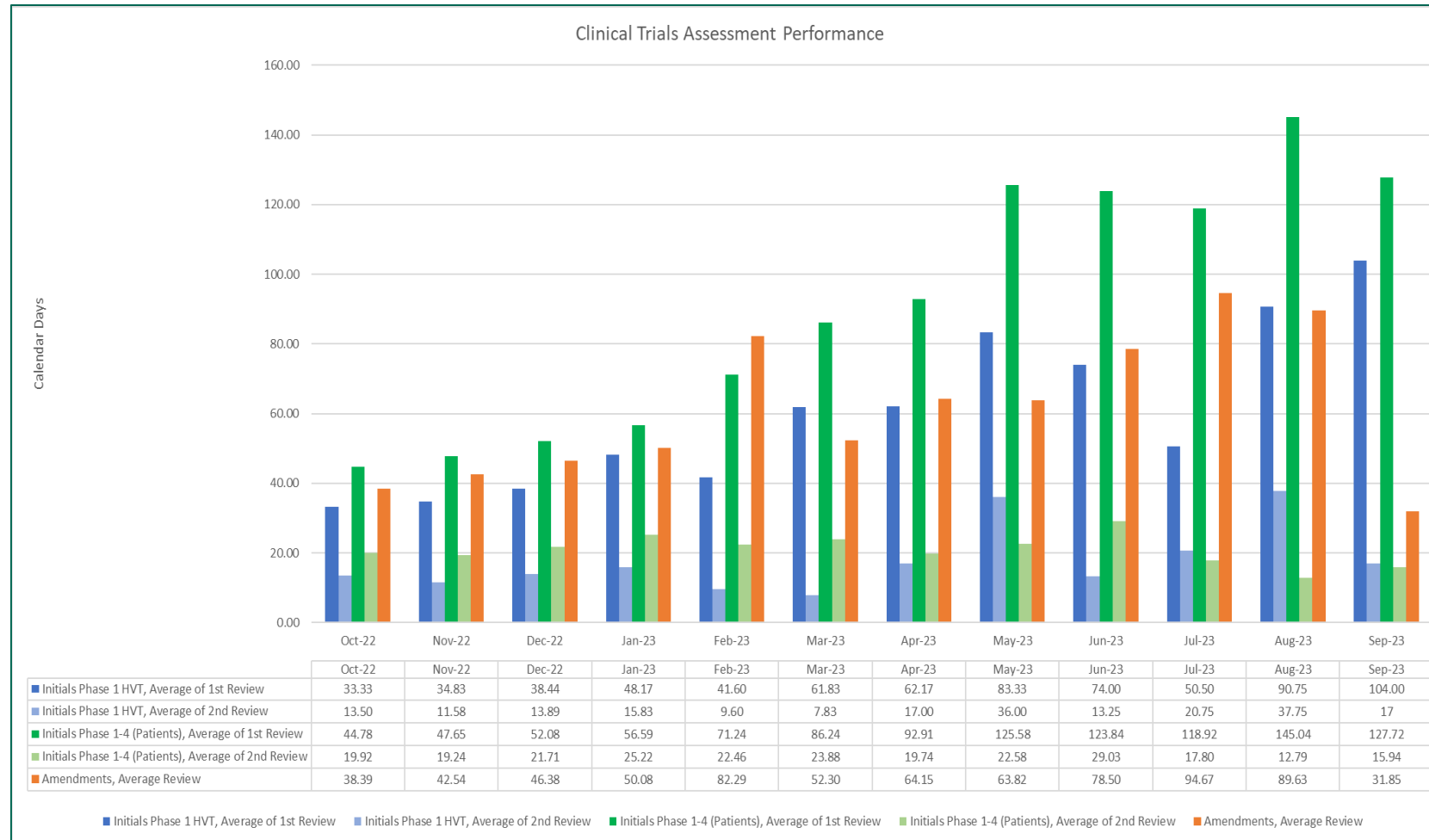
Number of applications

The number of initial CTA applications received in September 2023 increased compared with August 2023 (from 66 to 77 applications), while the number of substantial amendments received decreased (from 517 to 490 amendments). For both initial CTA applications and substantial amendments, the number of applications assessed in September 2023 decreased compared with August 2023 (93 compared with 320 initial applications, and 593 compared with 775 amendments).

Application timeframes

Applications submitted before
1 September 2023

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



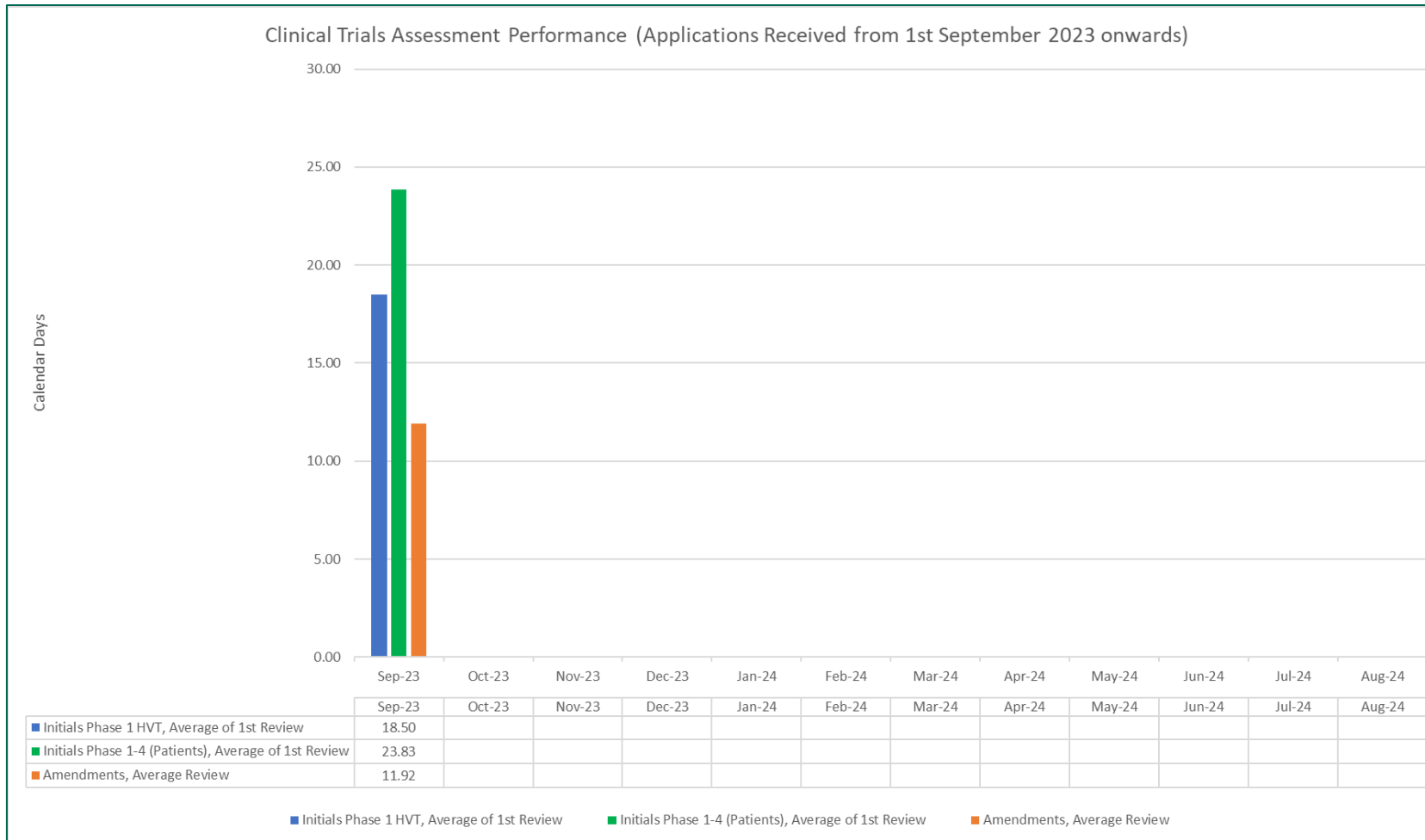
Key features

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).

Application timeframes

Applications submitted from
1 September 2023

Figure 2. Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued (day 30)) and substantial amendments (day 35)



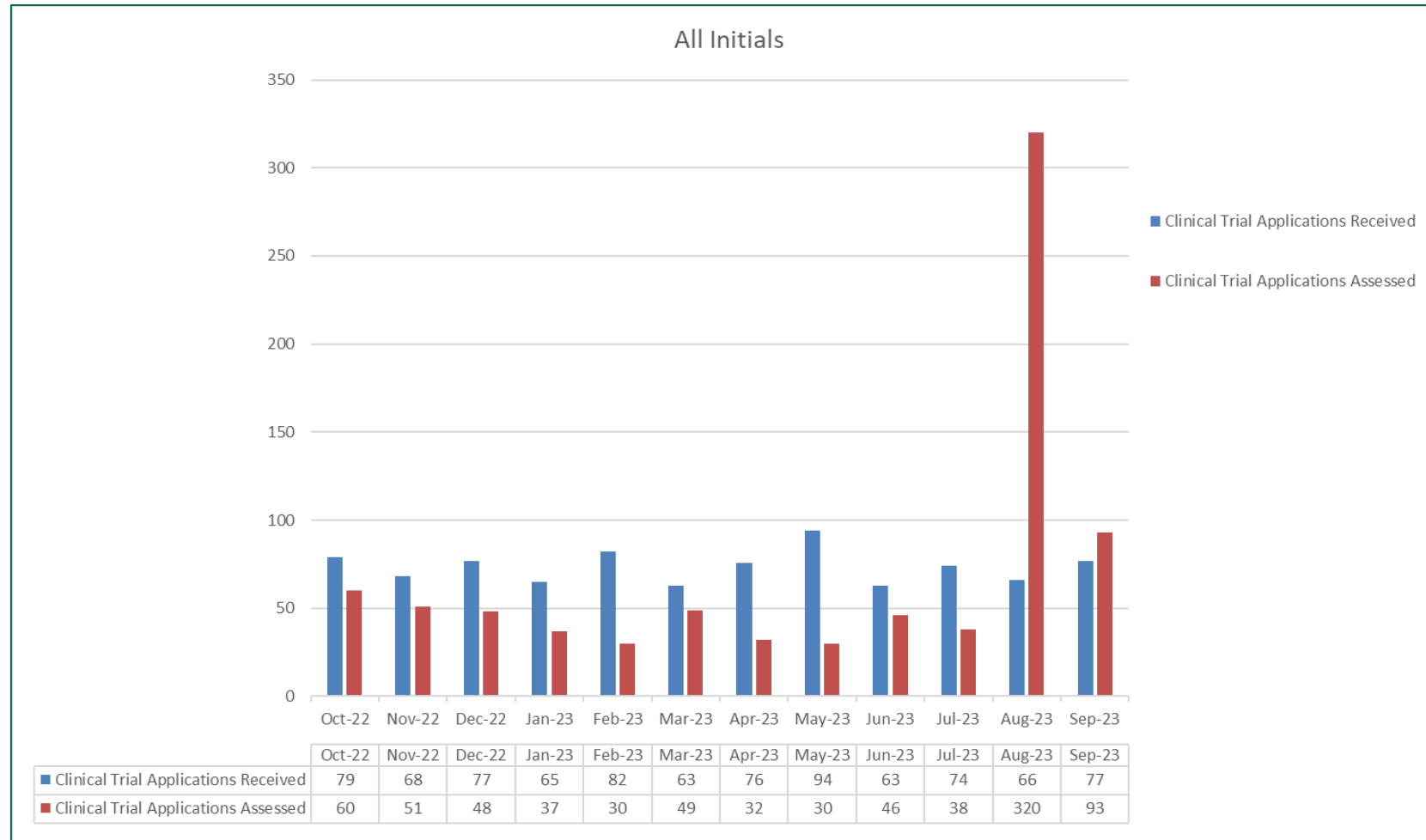
Key features

Figure 2 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. The monthly average for each category represents clinical trials for which were received from 1st September 2023 and the first review; from receipt of valid application to first opinion issued (day 30) for initials and substantial amendments (day 35).

Number of applications

Total received and assessed by month:
initials and amendments

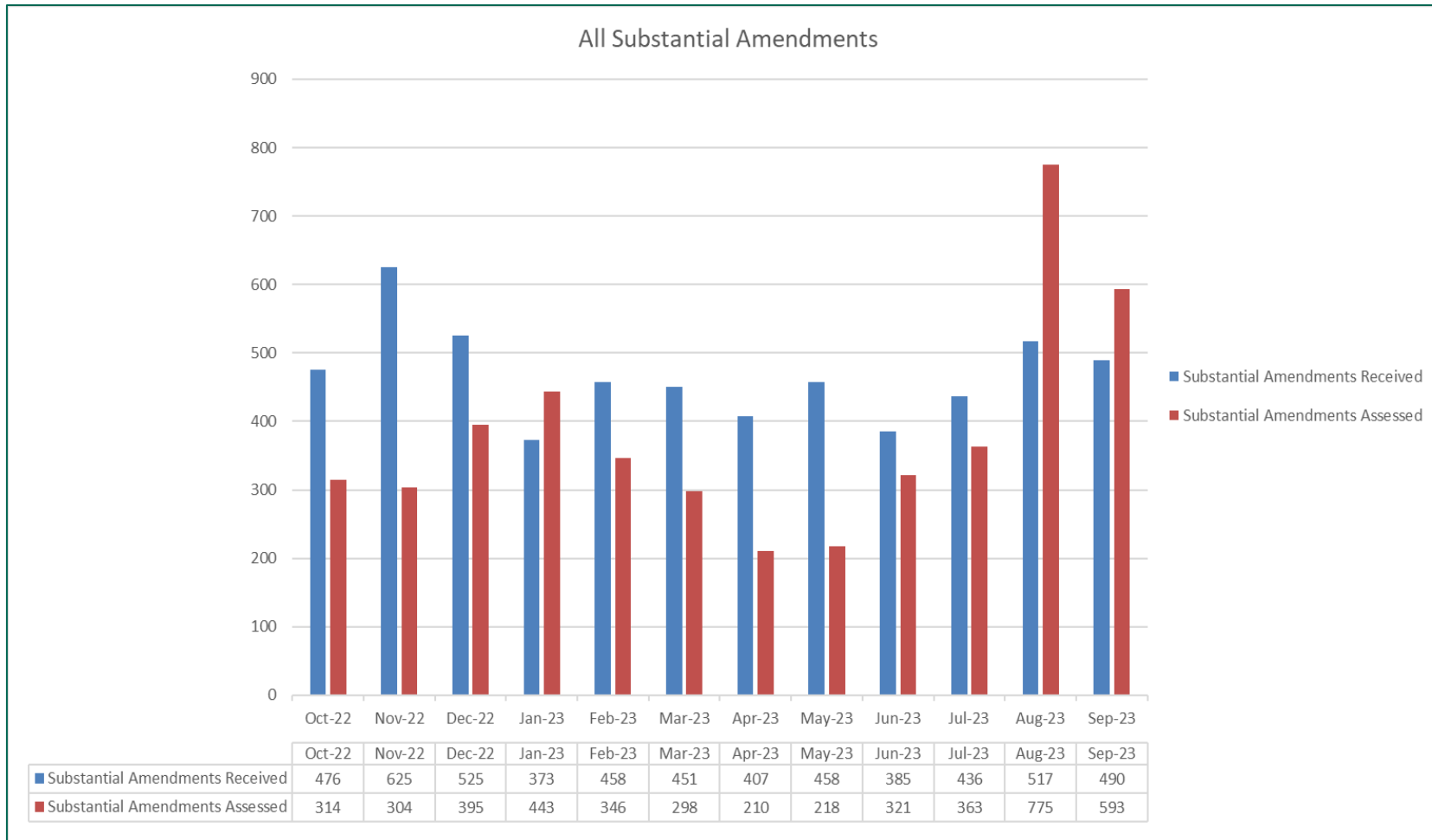
Figure 3. Number of clinical trial authorisation (CTA) applications ('initials') received and assessed by month (October 2022–September 2023)



Key features

Figure 3 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 4. Number of substantial amendments received and assessed by month (October 2022–September 2023)

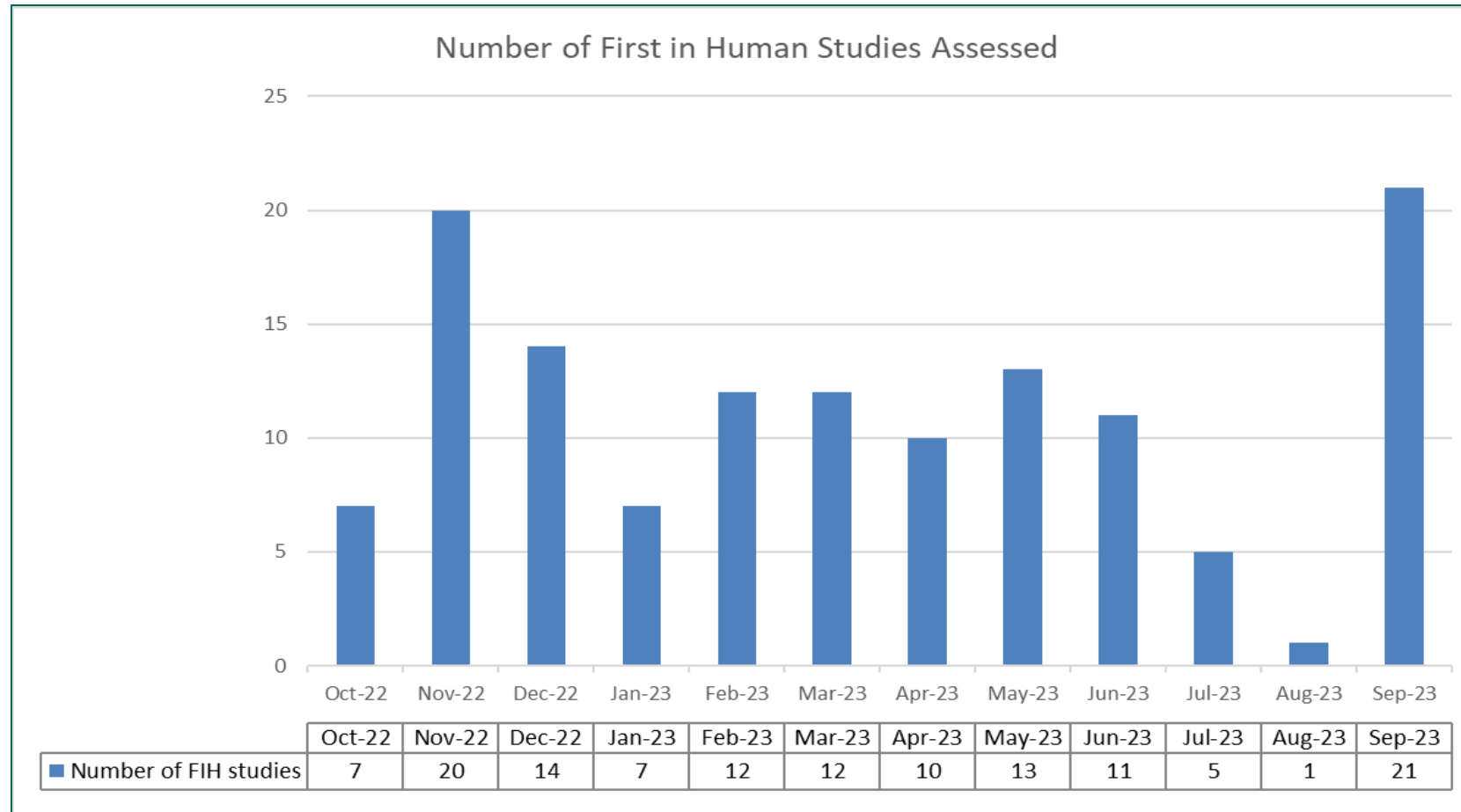


Key features
 Figure 4 shows the number of substantial amendments received and the number assessed in any given month. The number of amendments assessed for any given month is the number for which an opinion letter was issued in that month.

Number of initial applications assessed

By trial phase

Figure 5. Number of first-in-human CTA applications assessed by month (October 2022–September 2023)

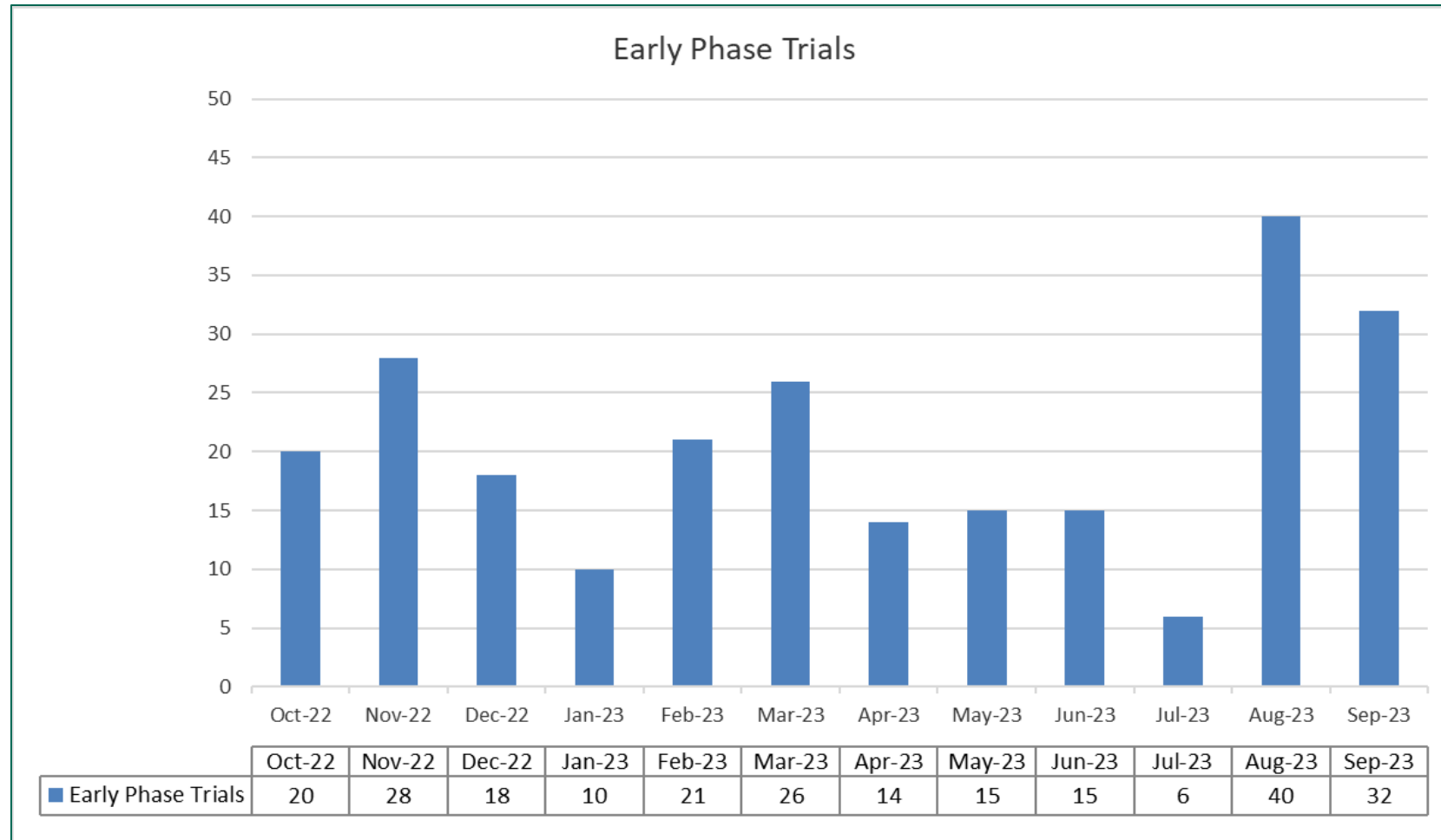


Key features

Figure 5 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)

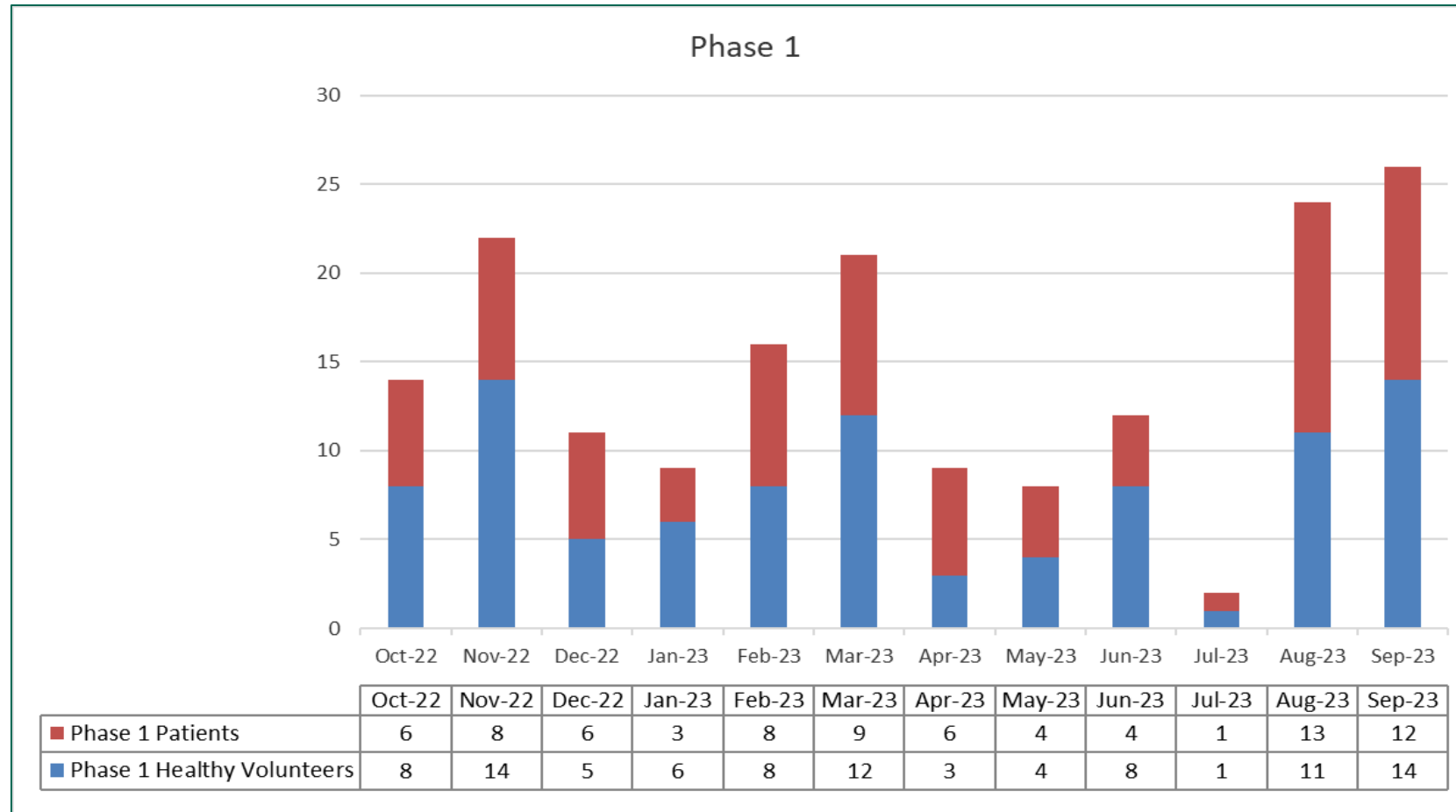
Figure 6. Number of early phase CTA applications assessed by month (October 2022–September 2023)



Key features

Figure 6 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).

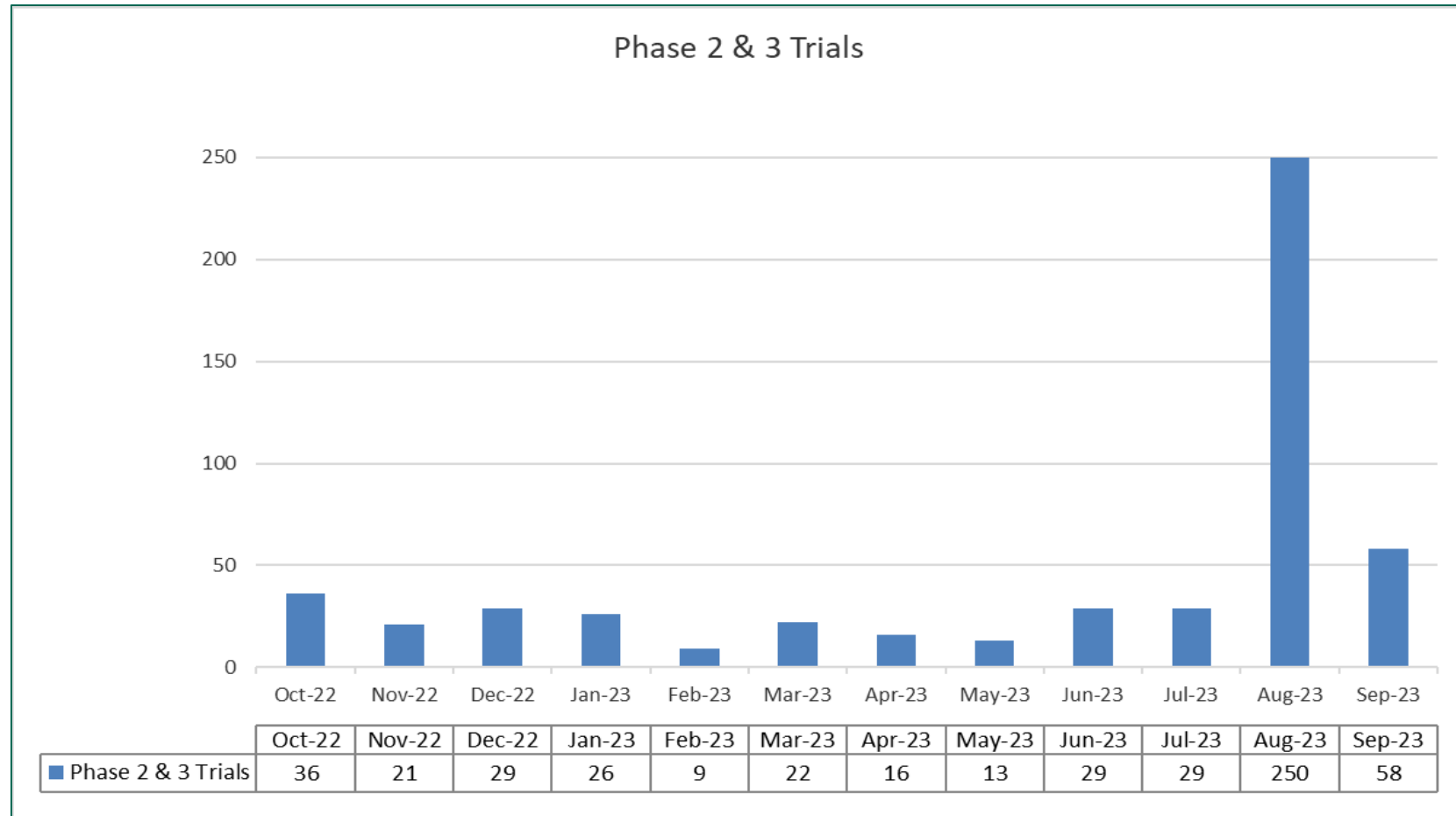
Figure 7. Number of phase 1 CTA applications assessed by month (October 2022–September 2023)



Key features

Figure 7 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).

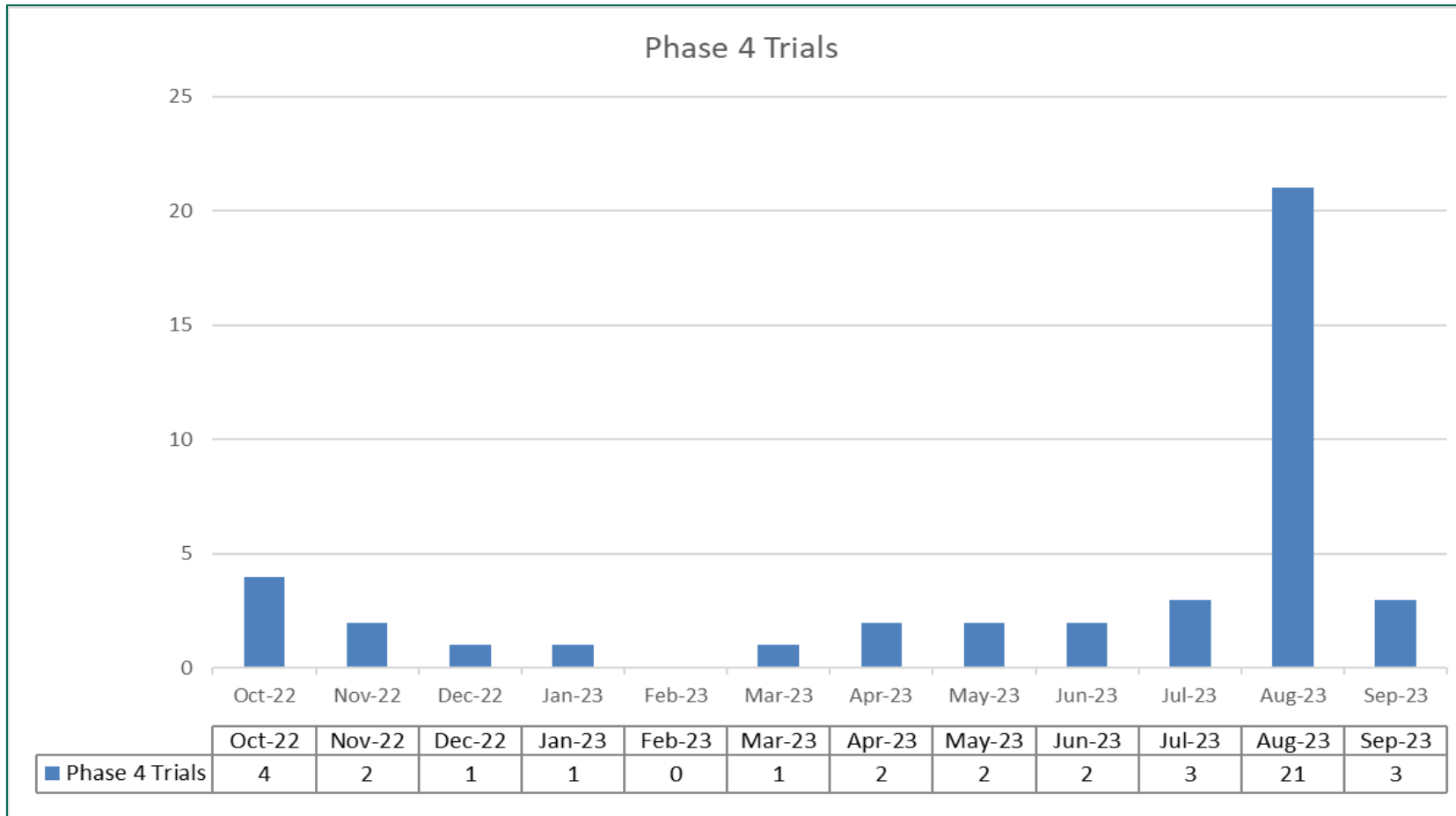
Figure 8. Number of phase 2 and 3 CTA applications assessed by month (October 2022–September 2023)



Key features

Figure 8 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 9. Number of phase 4 CTA applications assessed by month (October 2022–September 2023)



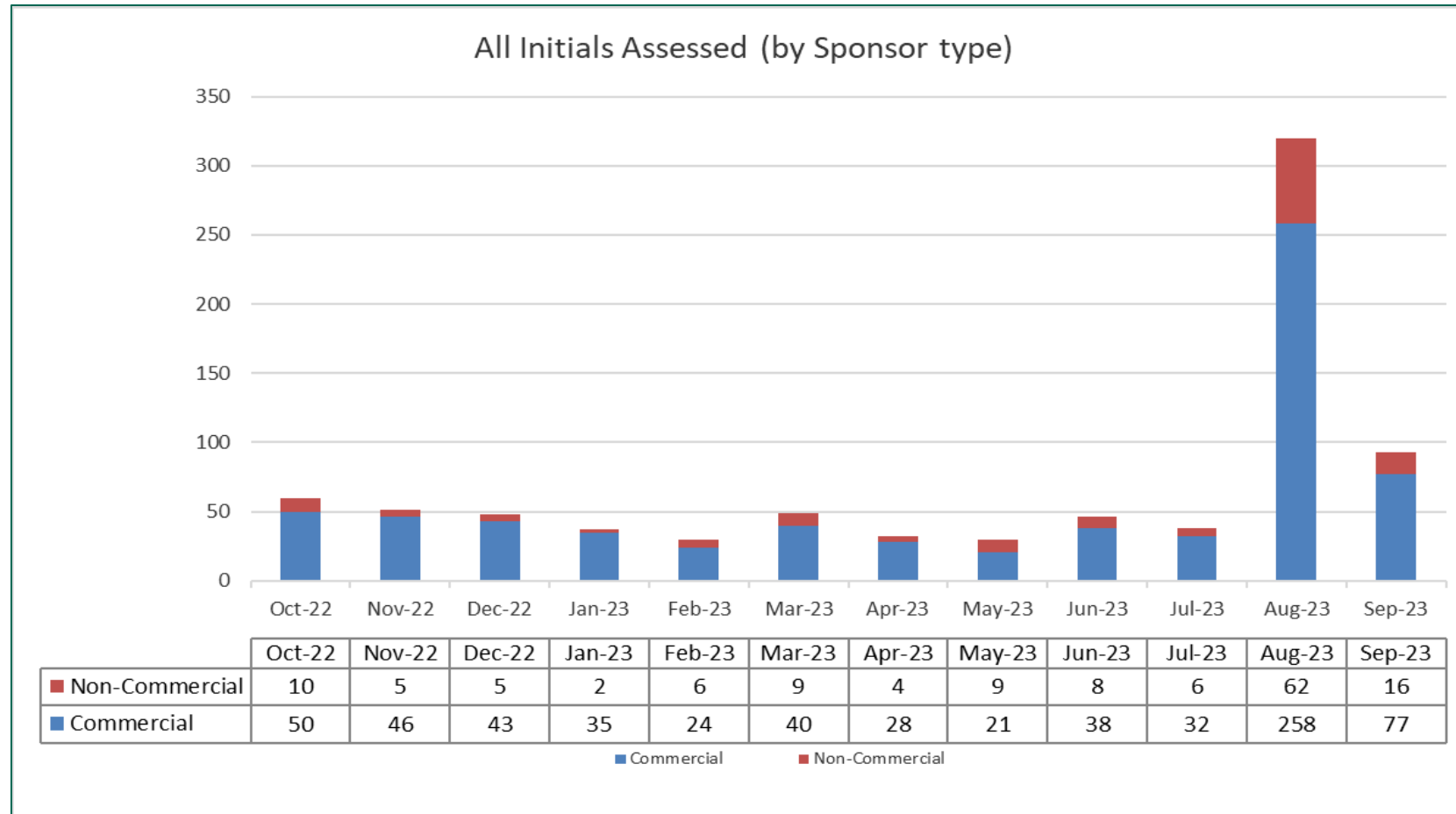
Key features

Figure 9 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).

Number of initial applications assessed

By sponsor type

Figure 10. Number of clinical trial authorisation (CTA) applications ('initials') assessed by sponsor type by month (October 2022–September 2023)



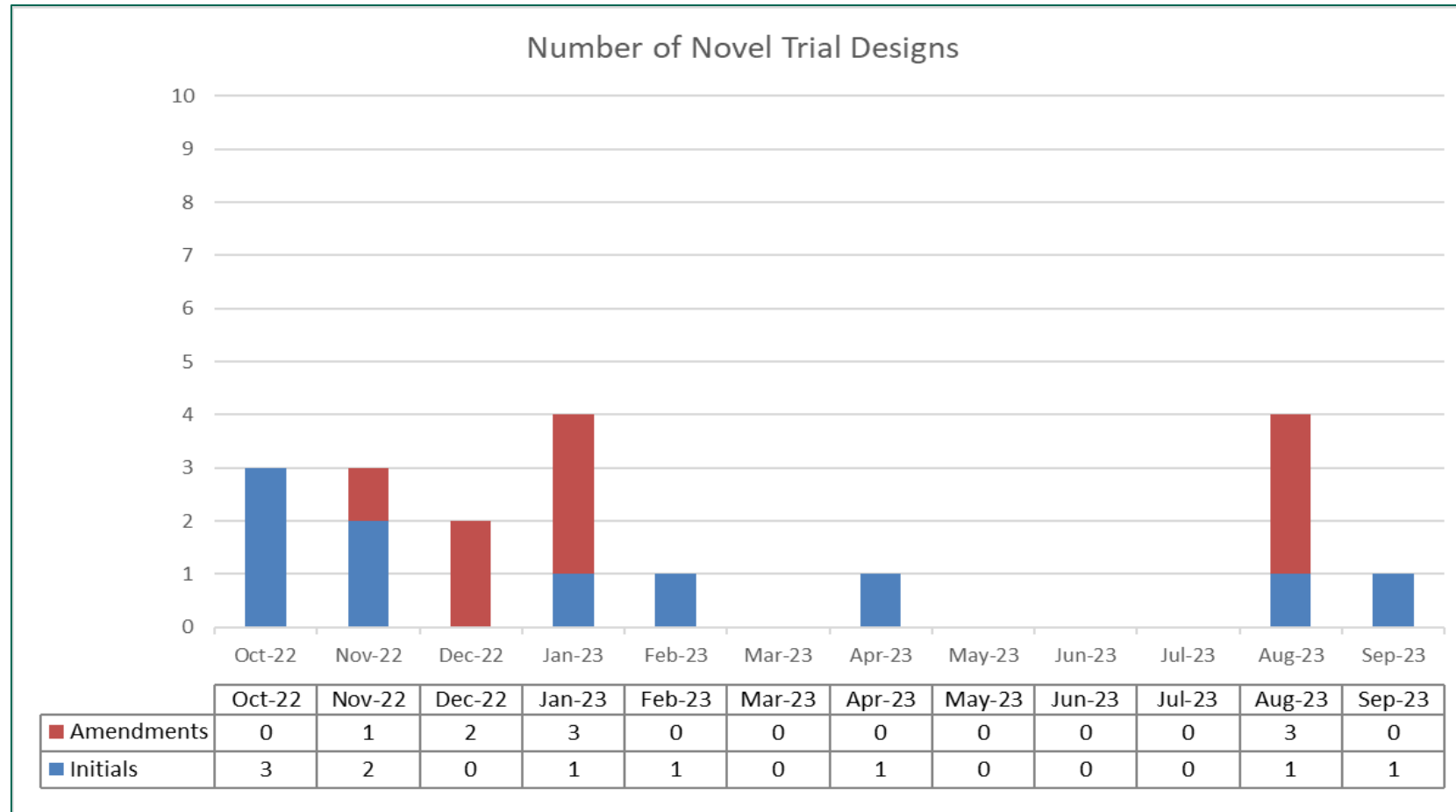
Key features

Figure 10 shows the number of clinical trial authorisation (CTA) applications assessed in any given month, split 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)

Number of initial and amendment applications assessed

Novel trial designs

Figure 11. Number of novel trial designs assessed by month: initial clinical trial authorisation (CTA) applications and amendments (October 2022–September 2023)



Key features

Figure 11 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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