Medicines & Healthcare products Regulatory Agency

Performance Metrics

Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments

December 2022 – November 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 and substantial amendments for applications submitted from 1 September 2023 onwards. (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 average timeline of Clinical Investigations applications and amendments for medical devices.

Summary of changes

Changes compared with the previous month

Summary of changes

Review times for clinical trials applications

Statutory timeframes continue to be met for all applications submitted after 1 September 2023, including the month of October 2023.

Number of applications

The number of initial CTA applications received in November 2023 increased compared with October 2023 (from 63 to 70 applications), while the number of substantial amendments received increased (from 479 to 499 amendments). For initial CTA applications, the number of applications assessed in November 2023 decreased compared with October 2023 (131 compared with 85 initial applications), while the number of substantial amendments assessed increased (352 compared with 388 amendments).

Review times for clinical investigations

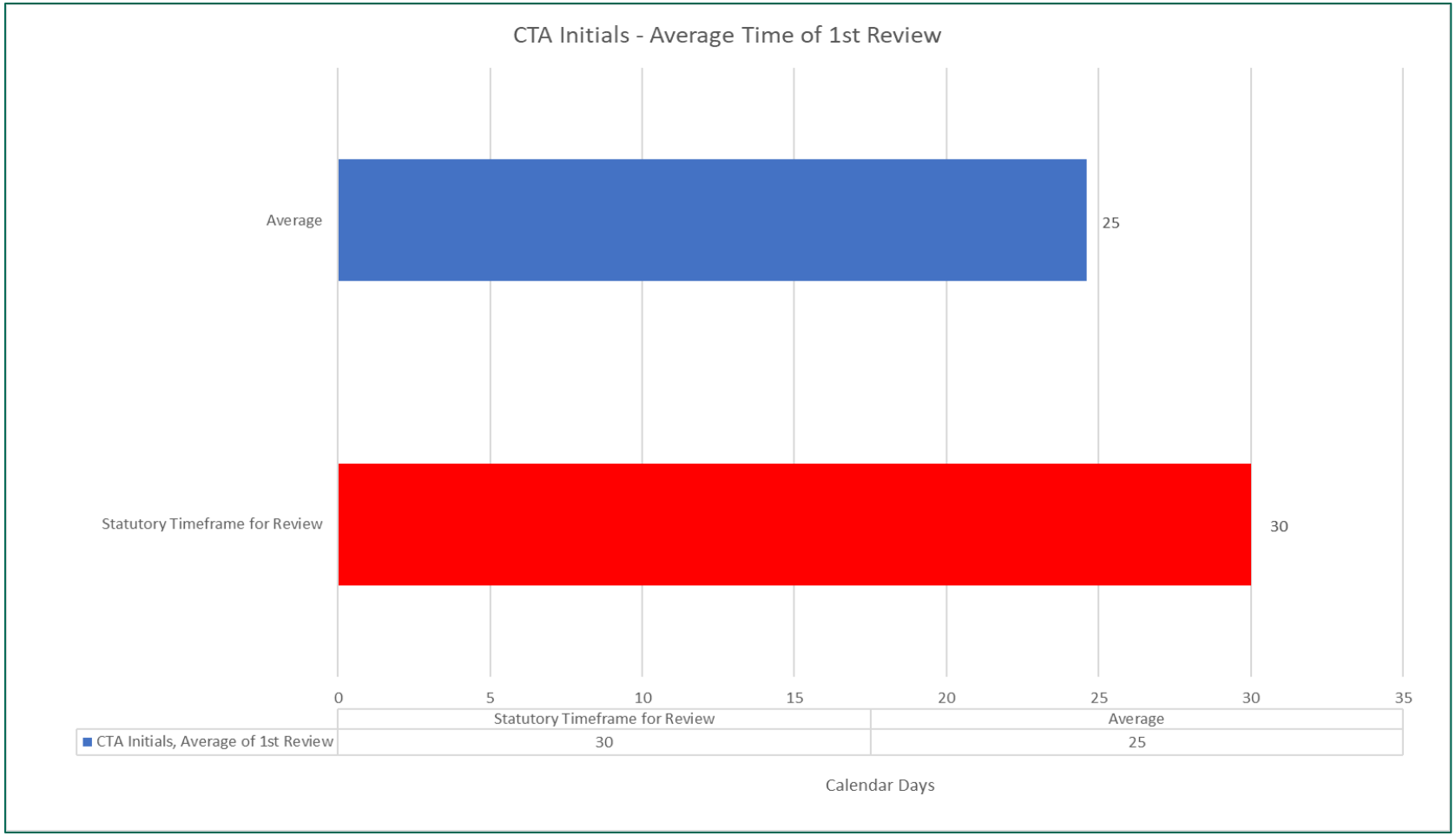
We are continuing to publish data on clinical investigations for Medical Devices.

Application timeframes

Clinical Trial Authorisation Applications

September 2023 – November 2023

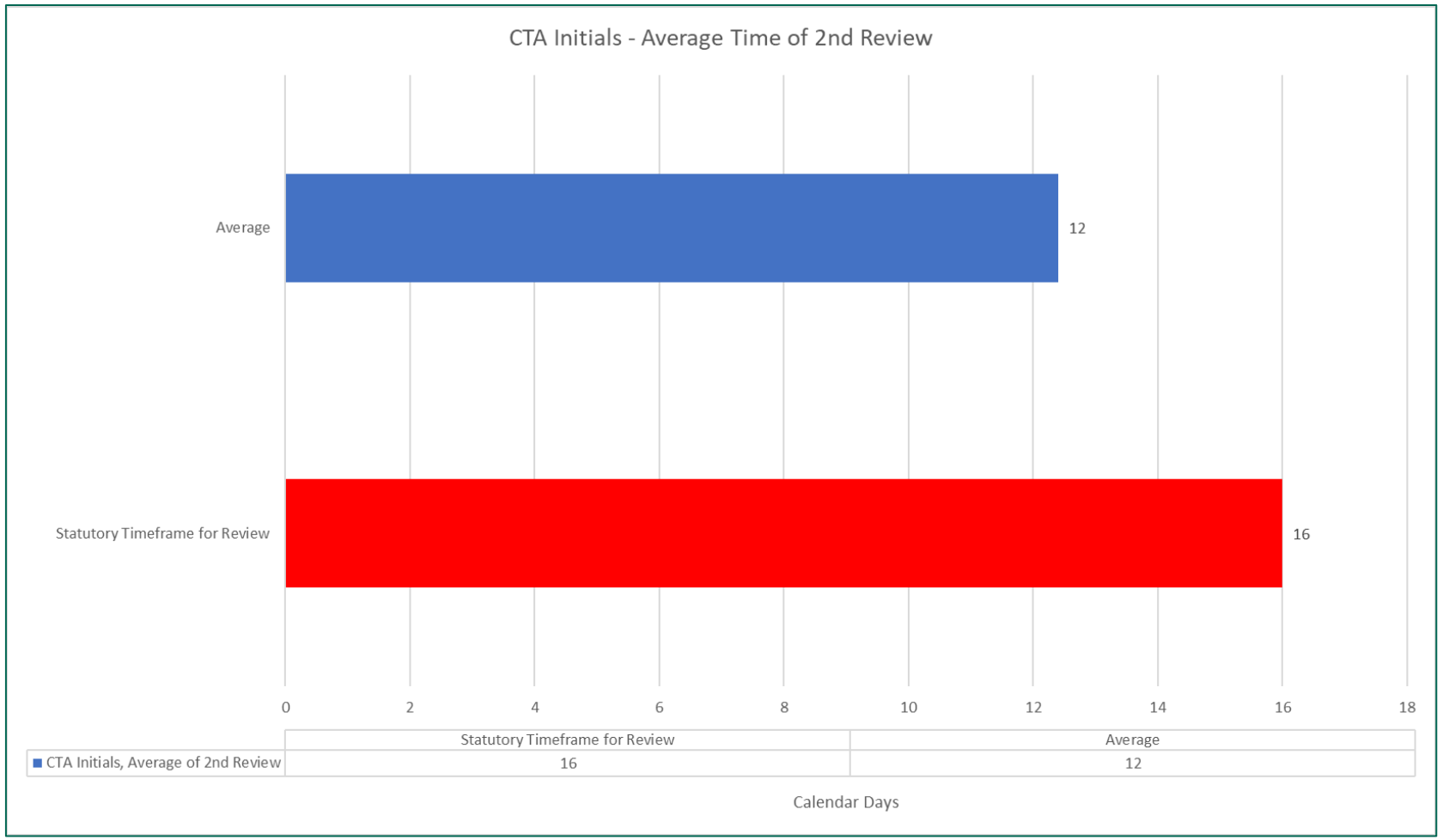
Figure 1. Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued (statutory timeframe for first review is day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



Key features

Figure 1 shows the average time taken for MHRA assessment of initial clinical trial applications. The average represents clinical trials which were received from 1st September 2023 onwards and the first review; from receipt of valid application to first opinion issued (statutory timeframe for first review is day 30) for initials.

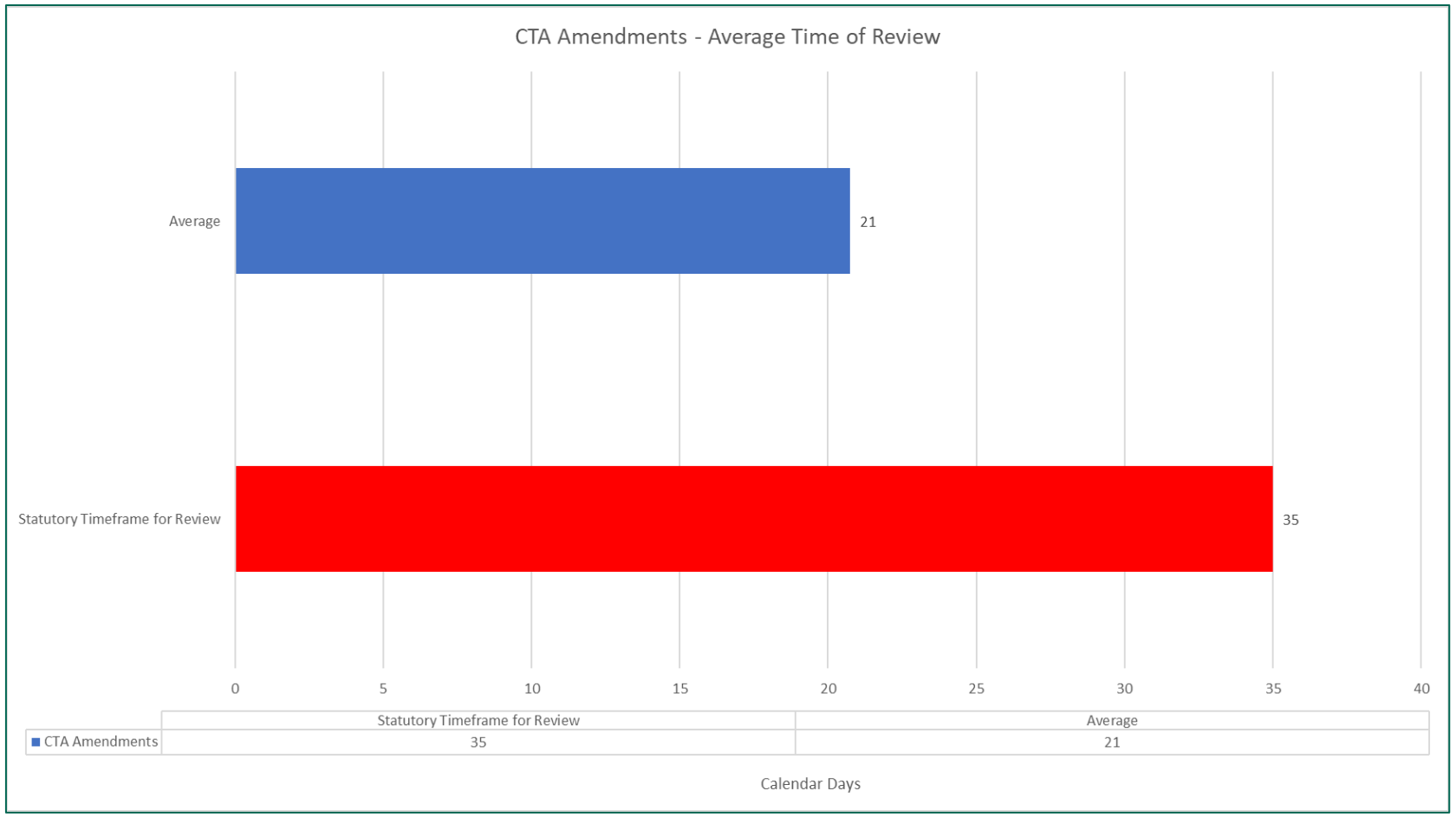
Figure 2. Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application second review (from receipt of applicant's response to Grounds for Non-Acceptance to outcome issued).



Key features

Figure 2 shows the average time taken for MHRA assessment of initial clinical trial applications. The average represents clinical trials which were received from 1st September 2023 onwards and the second review; from receipt of applicant's response to Ground for Non-Acceptance to outcome issued for initials.

Figure 3. Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: amendment clinical trial authorisation (CTA) application review (from receipt of valid application to outcome issued (statutory timeframe for review day 35)).



Key features

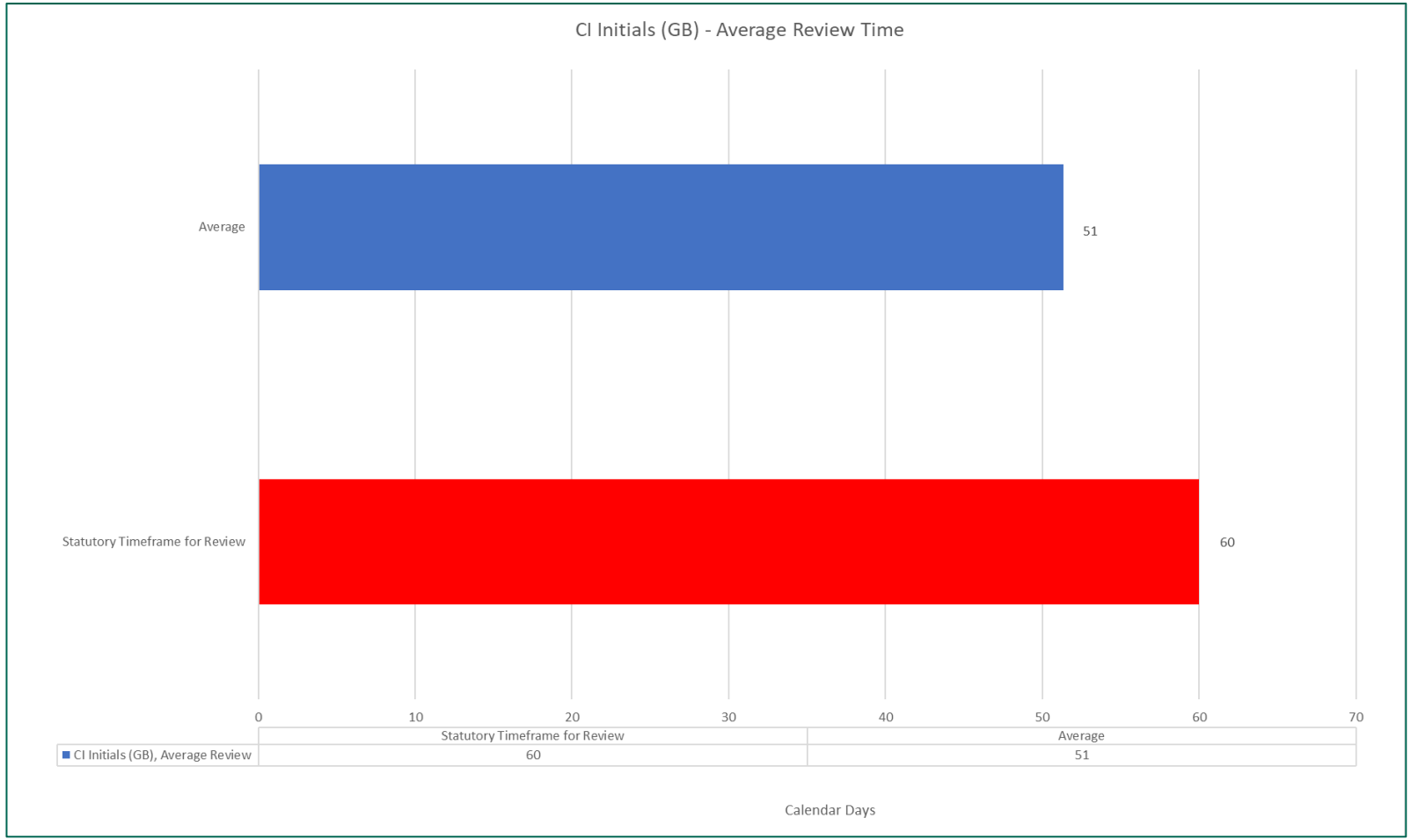
Figure 3 shows the average time taken for MHRA assessment of amendment clinical trial applications. This represents clinical trials which were received from 1st September 2023 and the outcome; from receipt of valid application of substantial amendment to outcome issued (statutory timeframe for first review day 35) for amendments.

Application timeframes

Clinical Investigation Applications

December 2022 – November 2023

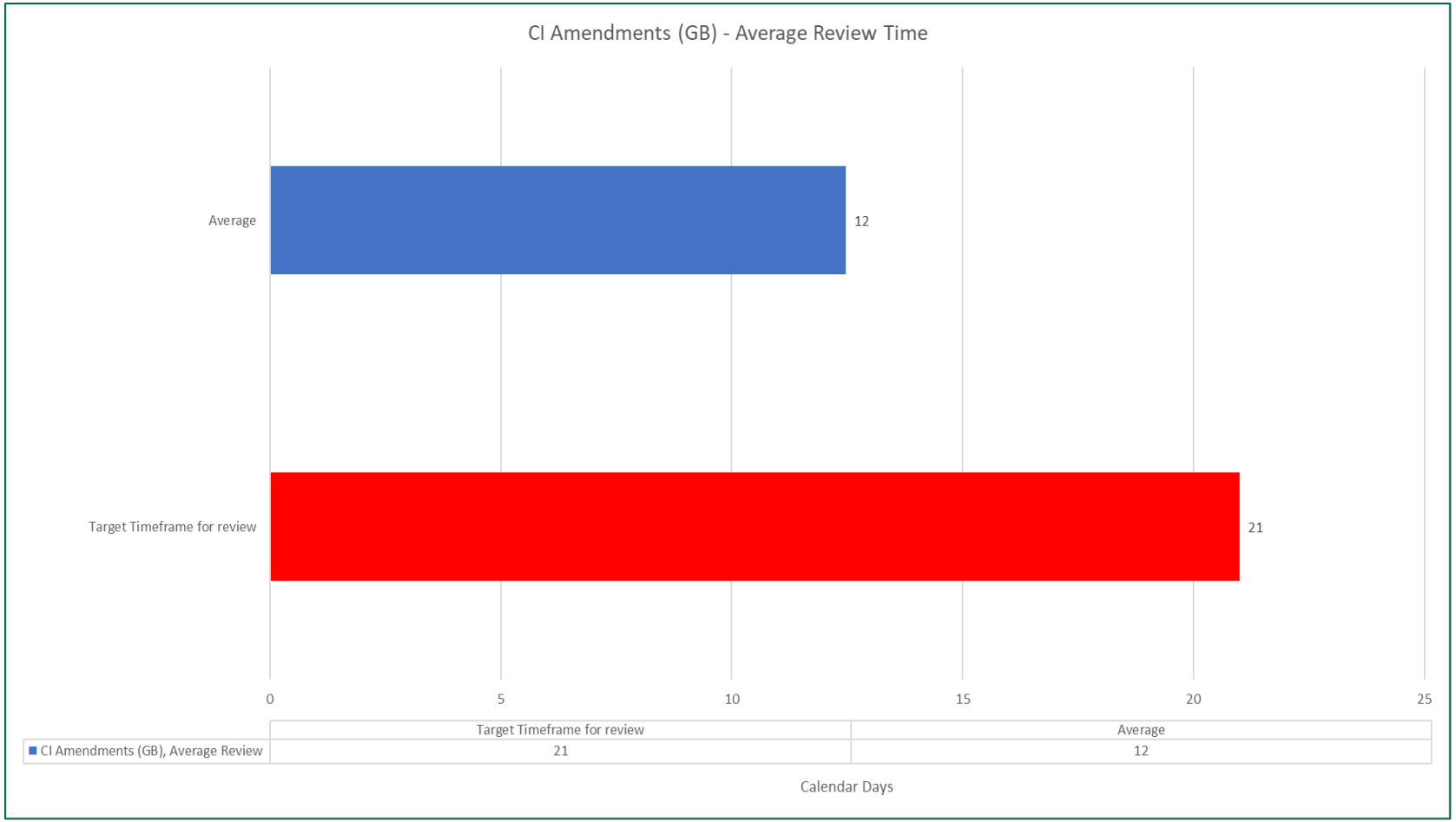
Figure 4. Average timeline (calendar days) for assessment of clinical investigation applications received from 1st December 2022 onwards for clinical studies carried out in GB: application review (from receipt of valid application to outcome issued (statutory timeframe for review day 60)).



Key features

Figure 4 shows the average time taken for MHRA assessment of initial clinical investigation applications. The average represents clinical investigations assessed for studies in GB (Great Britain); from receipt of valid application of clinical investigation to outcome issued (statutory timeframe for review day 60).

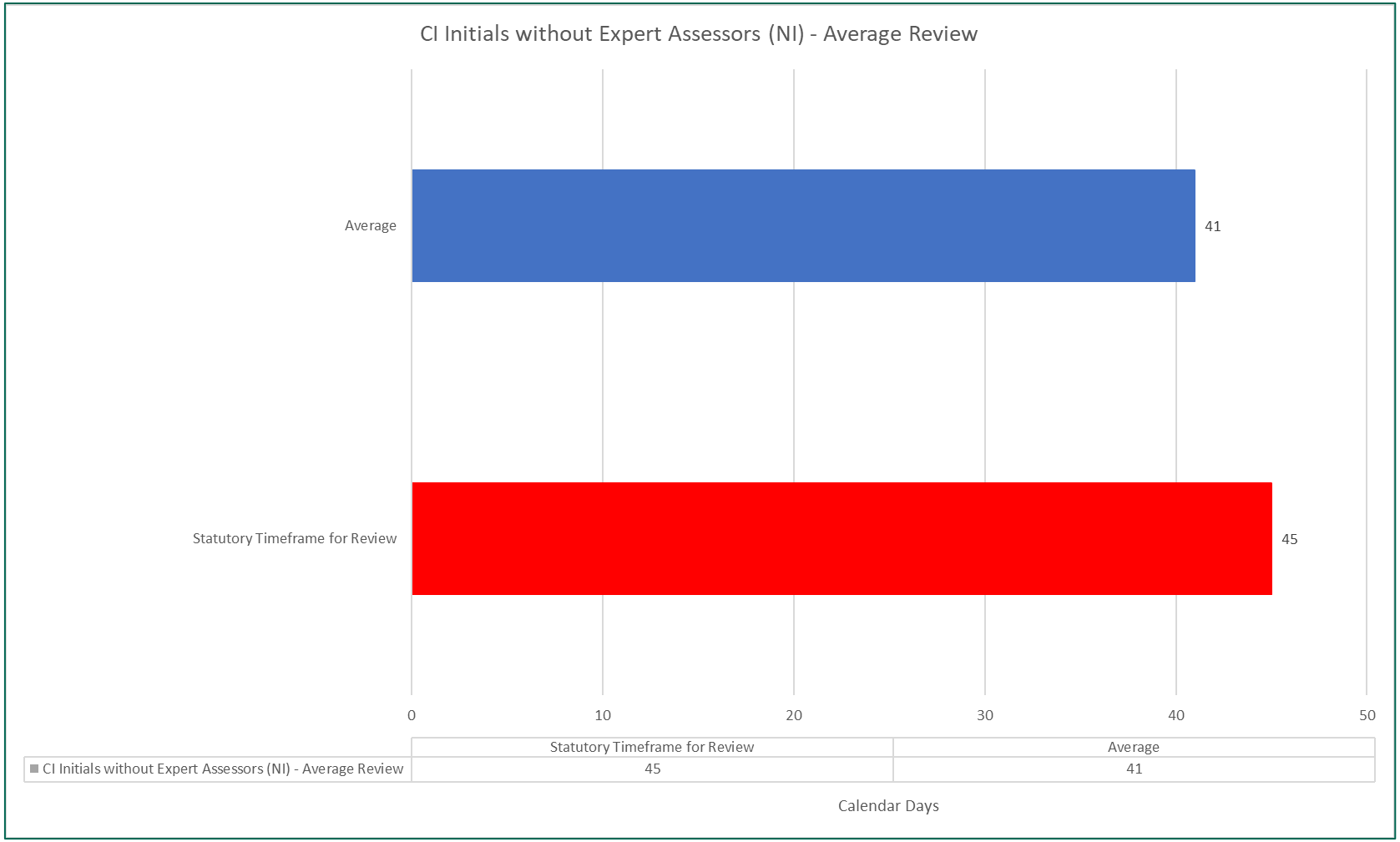
Figure 5. Average timeline (calendar days) for assessment of clinical investigation amendment applications received from 1st December 2022 for clinical studies carried out in GB: application review (from receipt of valid application to outcome issued (target for review day 21)).



Key features

Figure 5 shows the average time taken for MHRA assessment of clinical investigation amendment applications. The average represents clinical investigation amendment applications assessed for studies in GB (Great Britain); from receipt of valid application of clinical investigation amendment to outcome issued (target timeframe for review day 21).

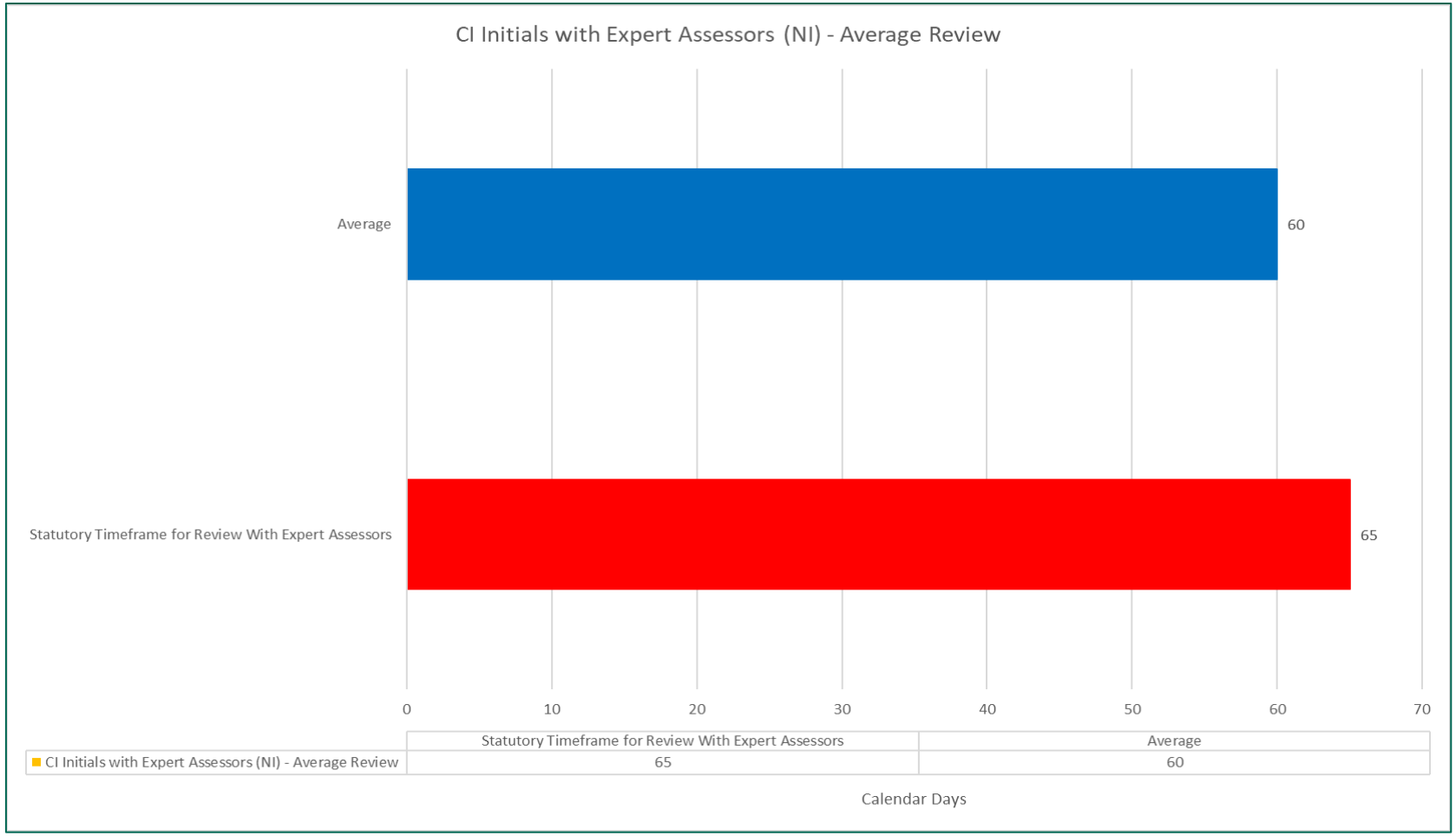
Figure 6. Average timeline (calendar days) for assessment of clinical investigation initial applications without expert assessors received from 1st December 2022 onwards for clinical studies carried out in NI: application review (from receipt of valid application to outcome issued (statutory timeframe for review day 45)).



Key features

Figure 6 shows the average time taken for MHRA assessment of clinical investigation initial applications for studies in NI (Northern Ireland). The average represents clinical investigation initial applications assessed for studies in NI from receipt of valid application of clinical investigation initial to outcome issued (statutory timeframe for review day 45).

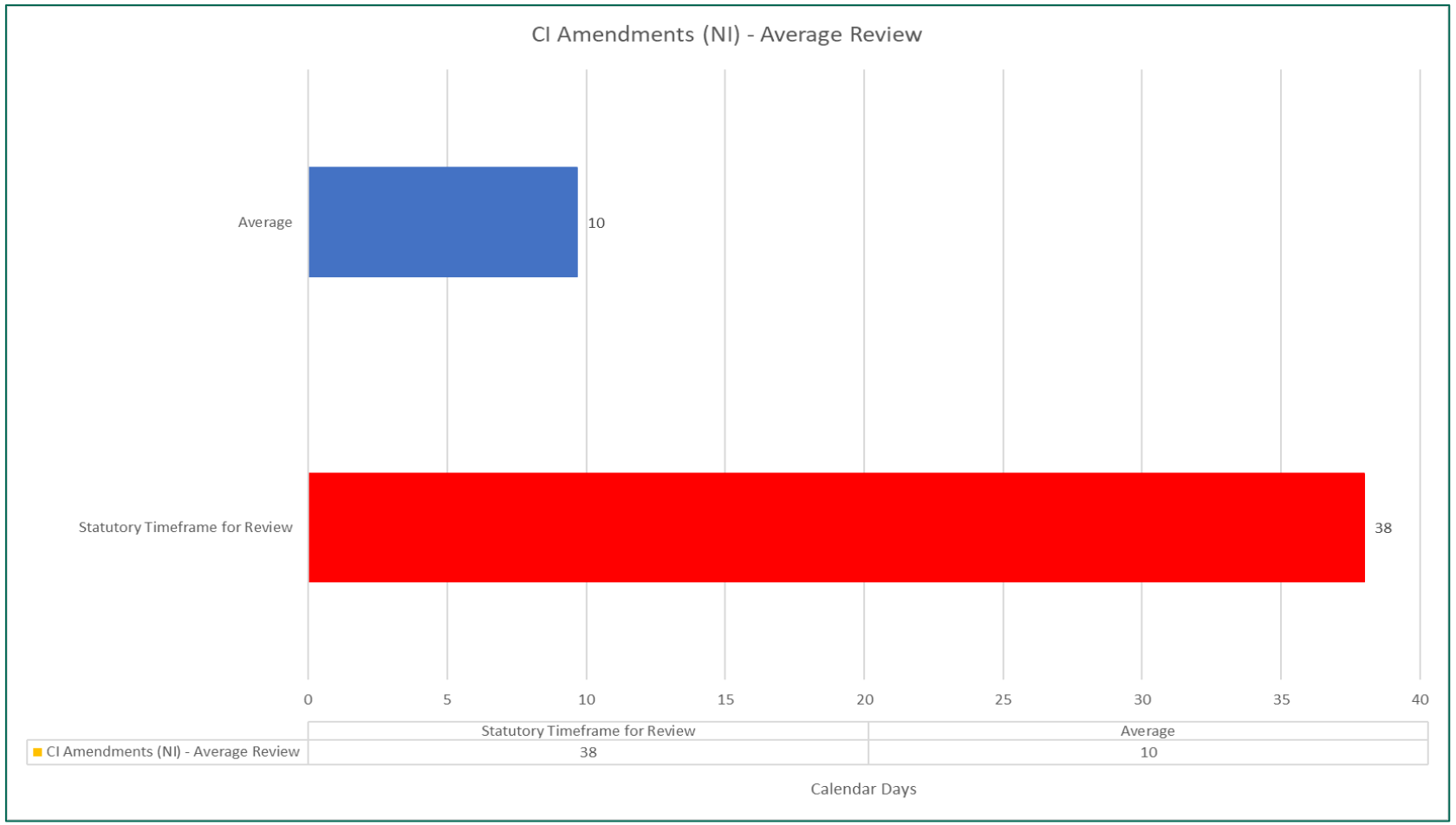
Figure 7. Average timeline (calendar days) for assessment of clinical investigation initial applications with expert assessors received from 1st December 2022 onwards for clinical studies carried out in NI: application review (from receipt of valid application to outcome issued (statutory timeframe for review day 65)).



Key features

Figure 7 shows the average time taken for MHRA assessment of clinical investigation initial applications for studies in NI (Northern Ireland). The average represents clinical investigation initial applications assessed for studies in NI from receipt of valid application of clinical investigation initial to outcome issued (statutory timeframe for review with expert assessor day 65).

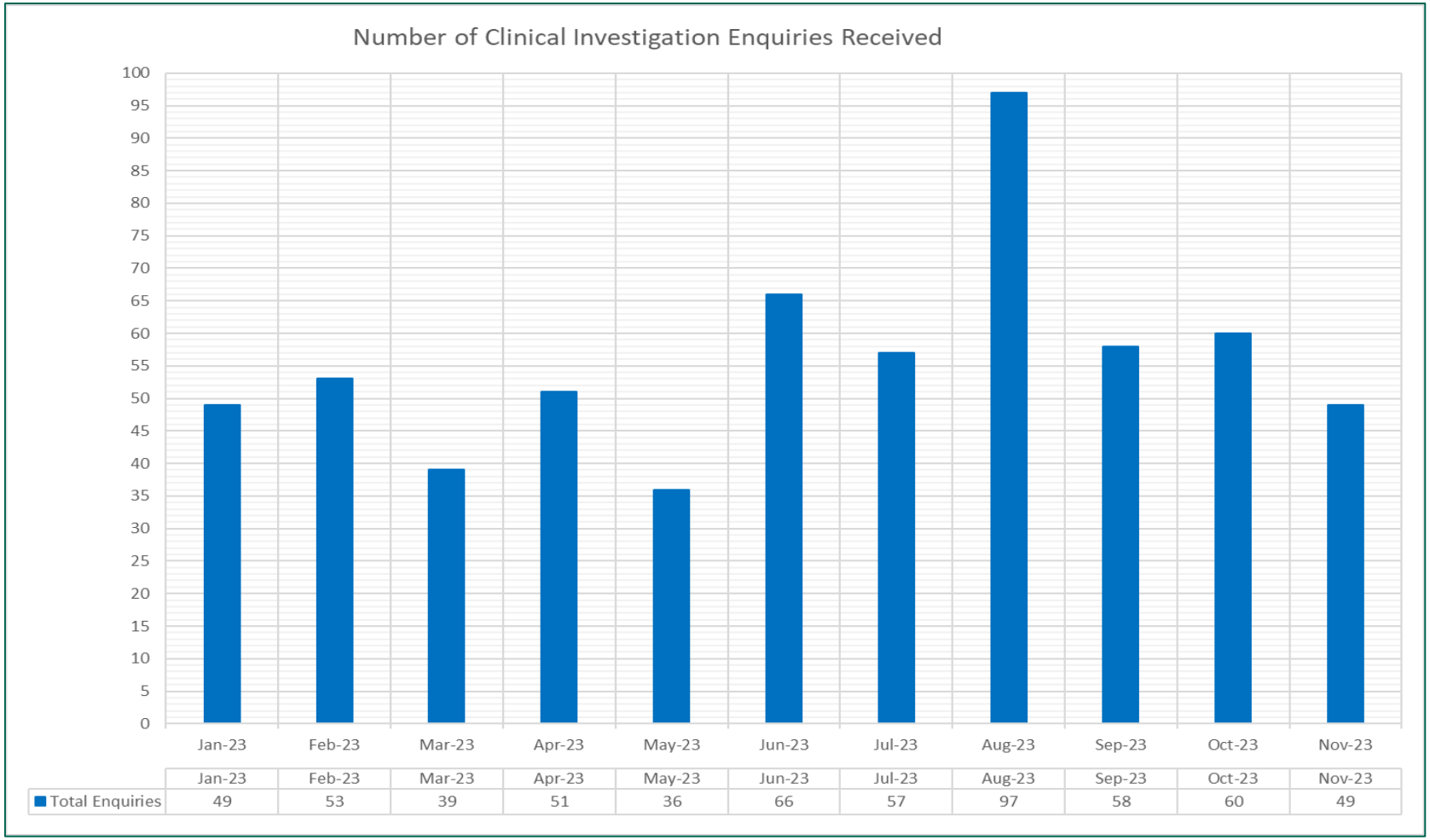
Figure 8. Average timeline (calendar days) for assessment of clinical investigation amendment applications received from 1st December 2022 for clinical studies carried out in NI: application review (from receipt of valid application to outcome issued (statutory timeframe for review day 38)).



Key features

Figure 8 shows the average time taken for MHRA assessment of clinical investigation amendment applications for studies in NI (Northern Ireland). The average represents clinical investigation amendment applications assessed for studies in NI from receipt of valid application of clinical investigation amendment to outcome issued (statutory timeframe for review day 38).

Figure 9. Number of clinical investigation enquiries received per month



	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23
Total Enquiries	49	53	39	51	36	66	57	97	58	60	49

Key features

Figure 9 shows the number of clinical investigation enquiries received per month for the year to date.

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