Medicines & Healthcare products Regulatory Agency

Performance Metrics

Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments

Clinical Trials: September 2023 – April 2024
Clinical Investigations: May 2023 – April 2024

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 April 2024.

Number of applications

The number of initial CTA applications received in April 2024 decreased compared with March 2024 (from 87 to 73 applications), and the number of substantial amendments received increased (from 463 to 471 amendments). For initial CTA applications, the number of applications assessed in April 2024 increased compared with March 2024 (48 compared with 57 initial applications), and the number of substantial amendments assessed increased (325 compared with 350 amendments).

Review times for clinical investigations

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

Application timeframes

Clinical Trial Authorisation Applications

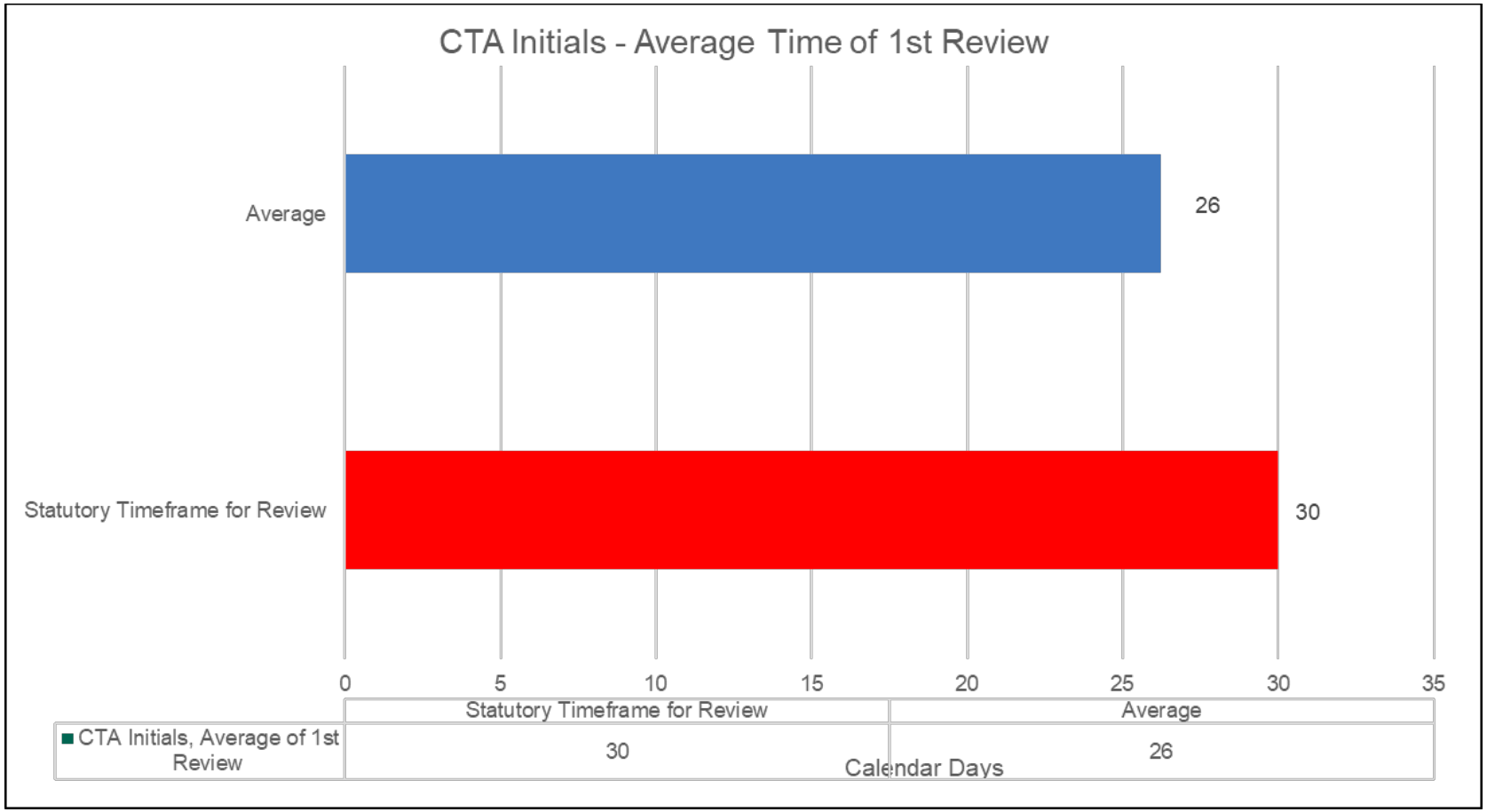
September 2023 – April 2024

Applications processed in April 2024

Submission type	Assessed	Statutory timelines
Initials	57	100%
Amendments	350	100%

- MHRA targets are to complete assessment of 98% clinical trial applications within statutory timeframes as outlined in the 2023/24 business plan (ref PM1a).
- There is a difference between the number of applications received and assessed which is due to the statutory timeline.

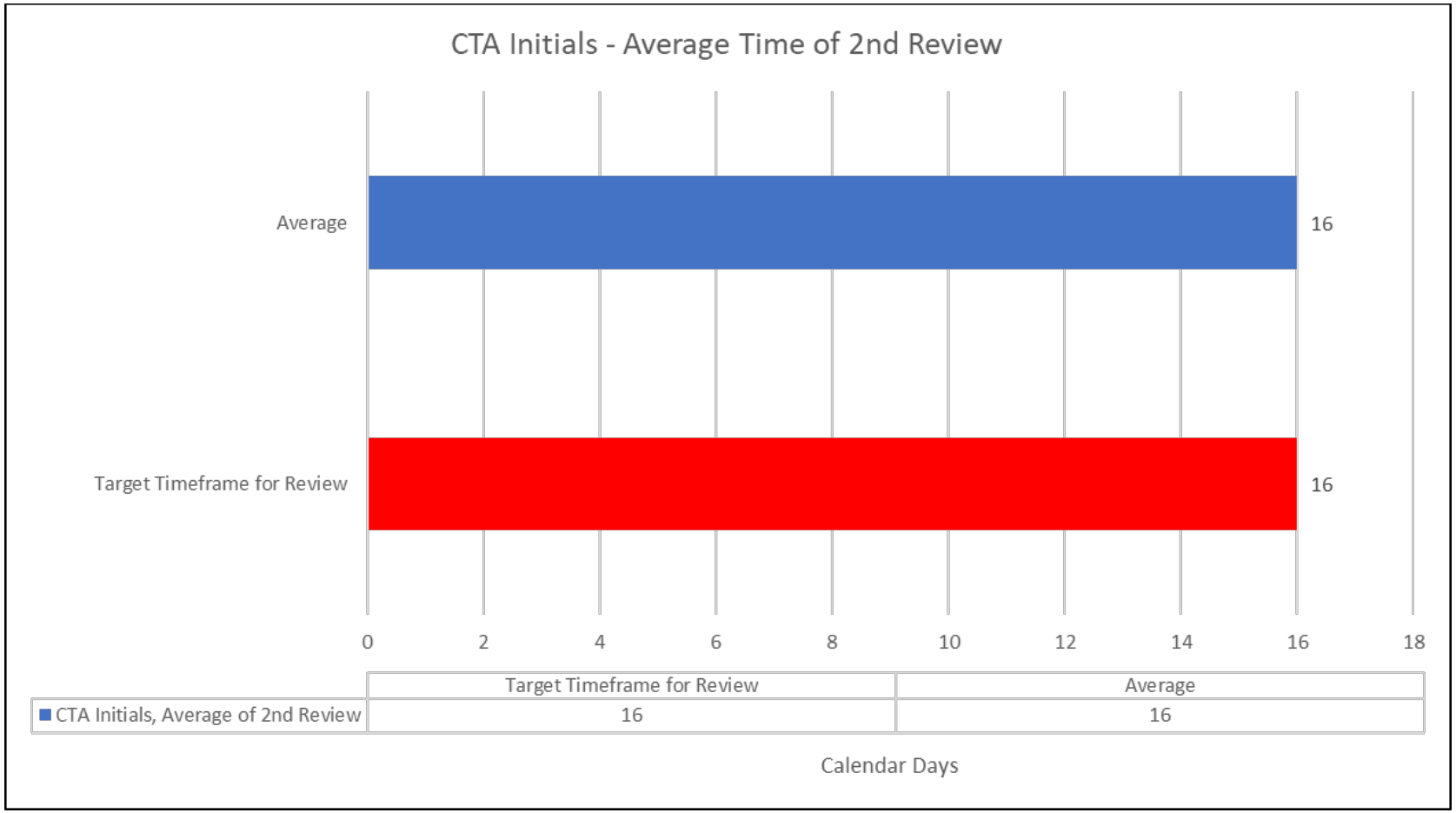
Figure 1. Average timeline (calendar days) for assessment of clinical trial applications received from 1 September 2023 onwards: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued (statutory timeframe for first review is day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

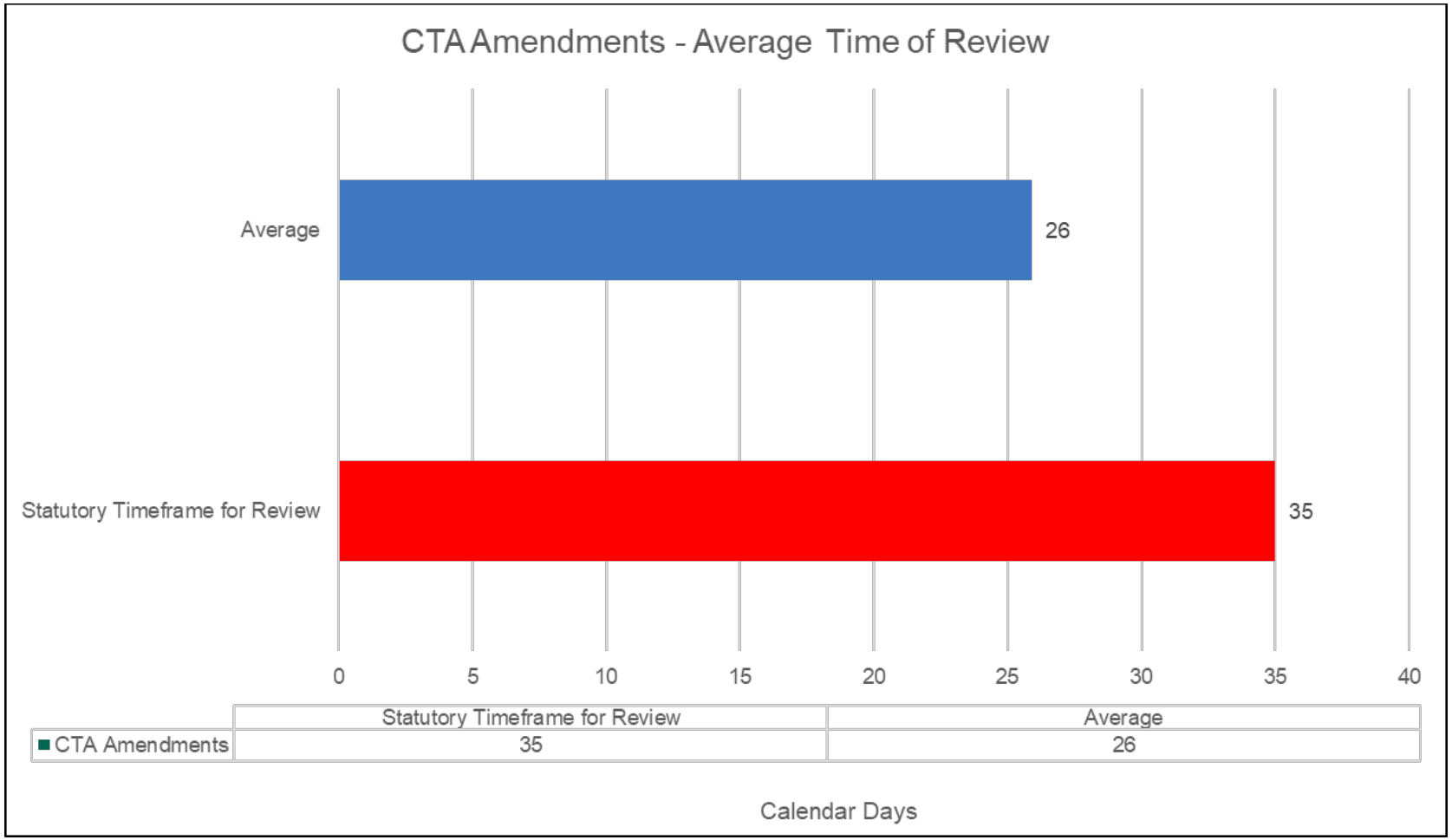
Figure 2. Average timeline (calendar days) for assessment of clinical trial applications received from 1 September 2023 onwards: initial clinical trial authorisation (CTA) application second review (from receipt of applicant's response to Grounds for Non-Acceptance to outcome issued).



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 1 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

May 2023 – April 2024

Clinical Investigations processed in April 2024

Submission type	Assessed	Statutory timelines
Initials	7 (GB)	in target 100%
Amendments	12 (GB), 1 (GBNI)	in target 100%

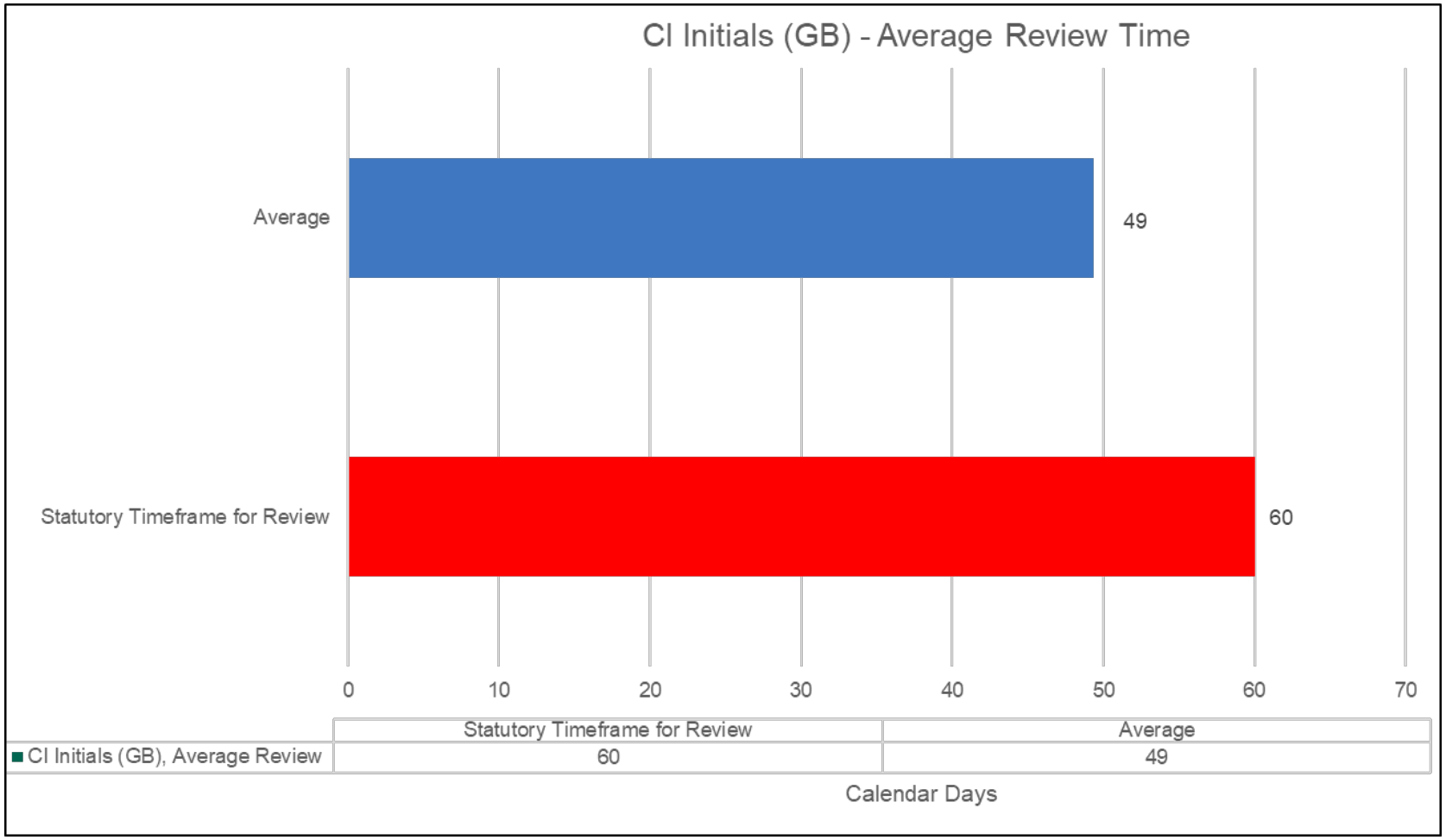
Key

GB= Great Britain

GBNI= Great Britain and Northern Ireland

There is a difference between the number of applications received and assessed which is due to the statutory timeline.

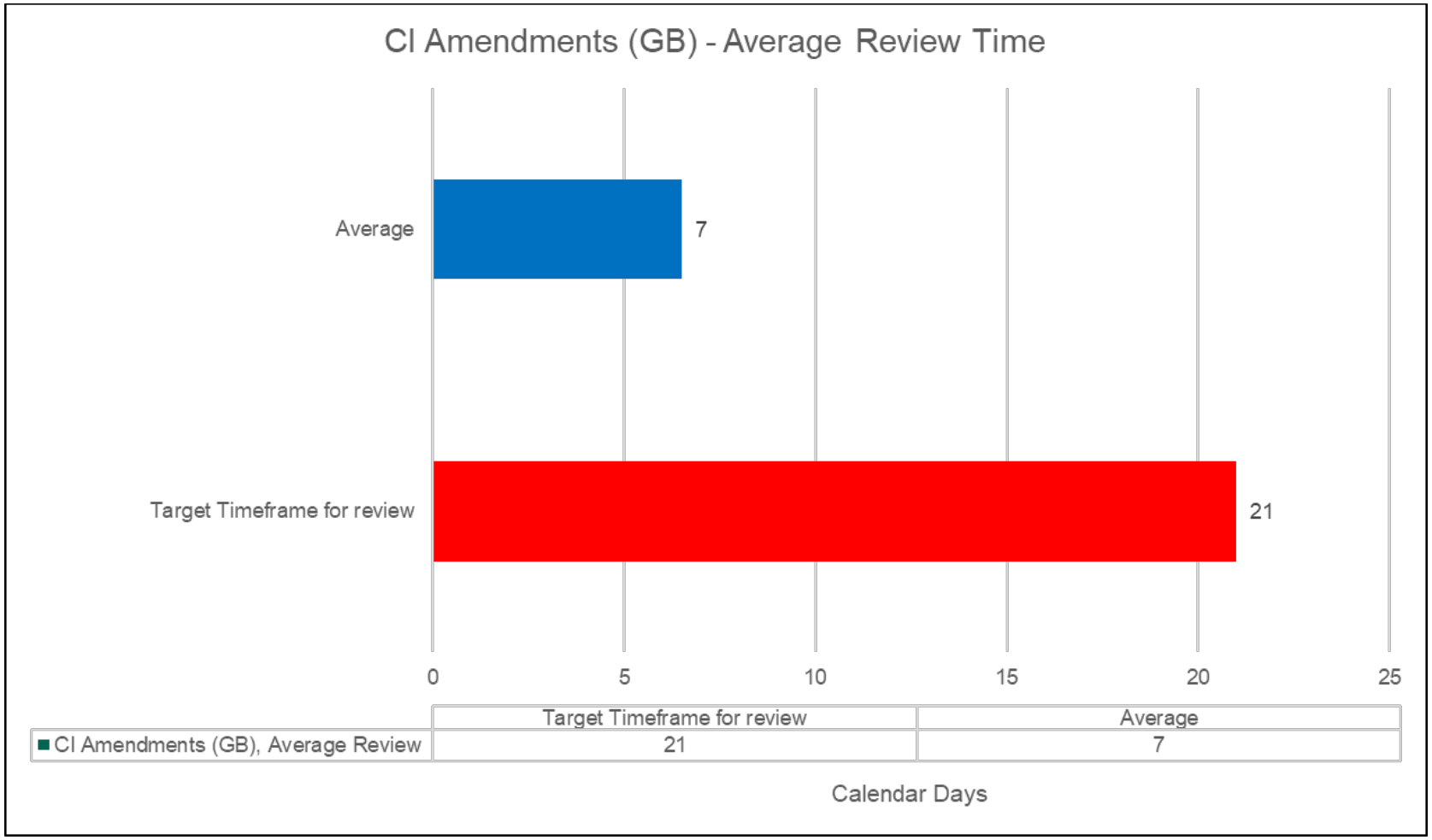
Figure 4. Average timeline (calendar days) for assessment of clinical investigation applications received from 1 May 2023 onwards for clinical studies carried out in GB: application review (from receipt of valid application to outcome issued (statutory timeframe for review day 60)).



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).

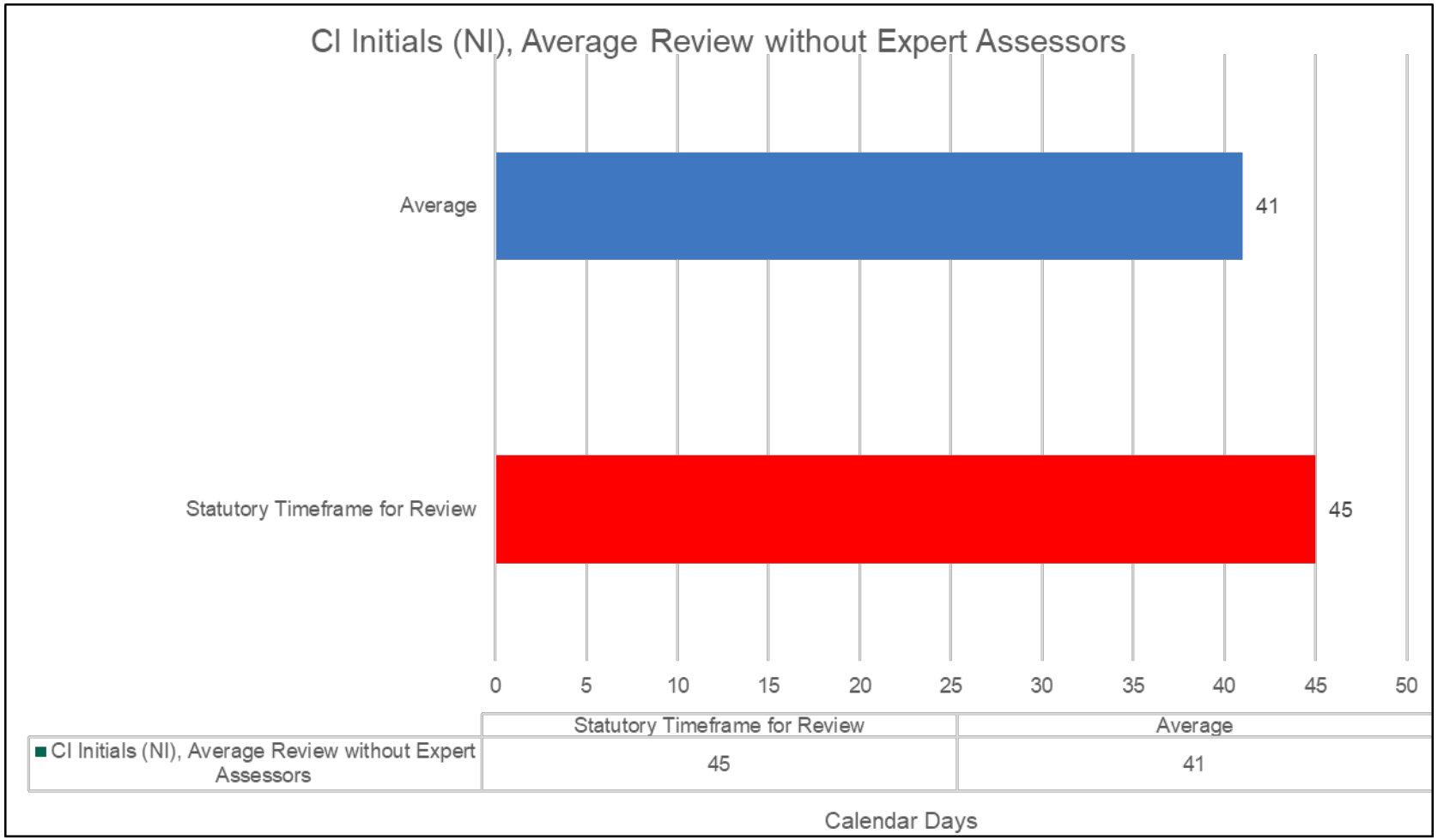
Figure 5. Average timeline (calendar days) for assessment of clinical investigation amendment applications received from 1 May 2023 for clinical studies carried out in GB: application review (from receipt of valid application to outcome issued (target for review day 21)).



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).

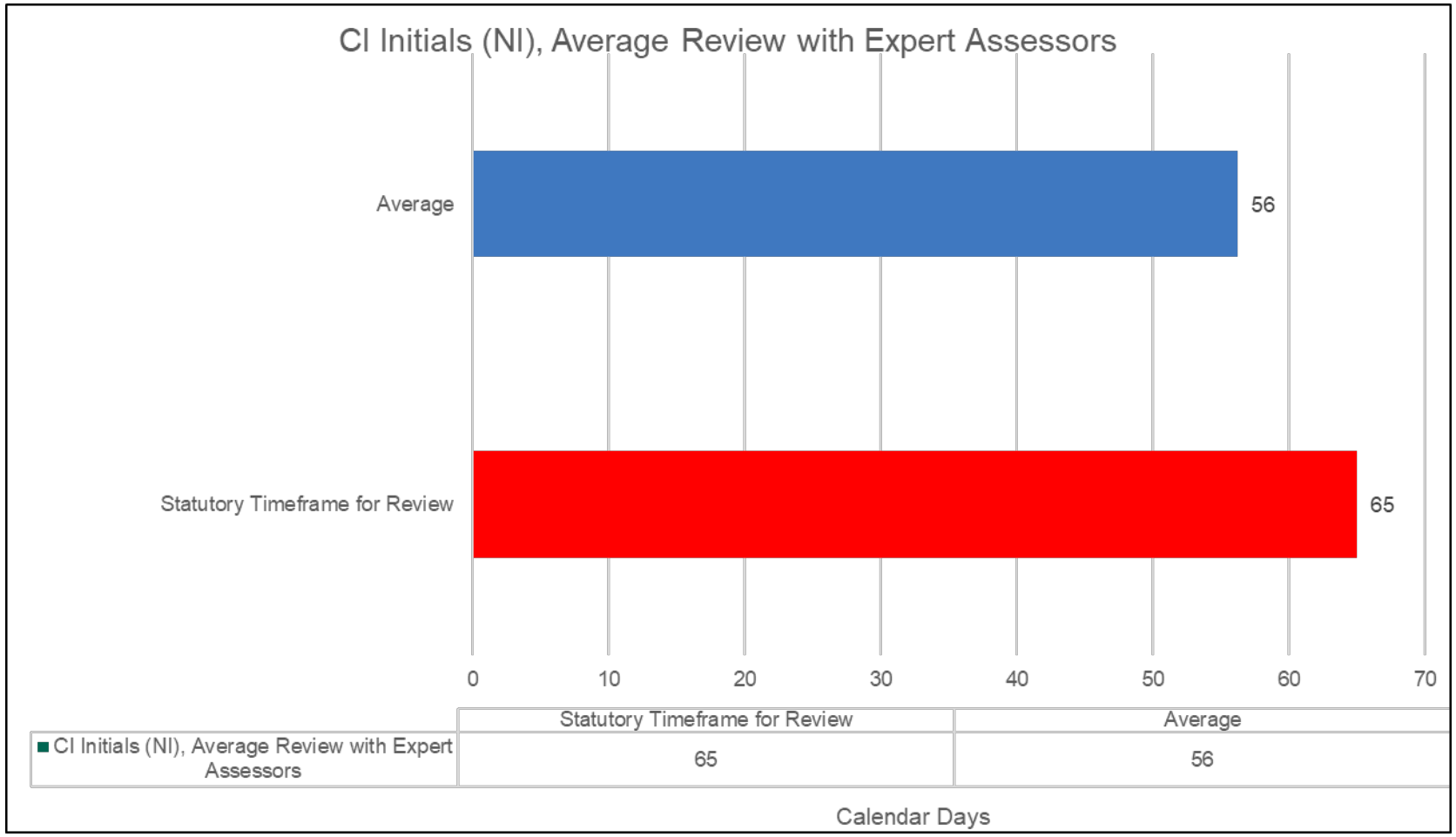
Figure 6. Average timeline (calendar days) for assessment of clinical investigation initial applications without expert assessors received from 1 May 2023 onwards for clinical studies carried out in NI: application review (from receipt of valid application to outcome issued (statutory timeframe for review 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).

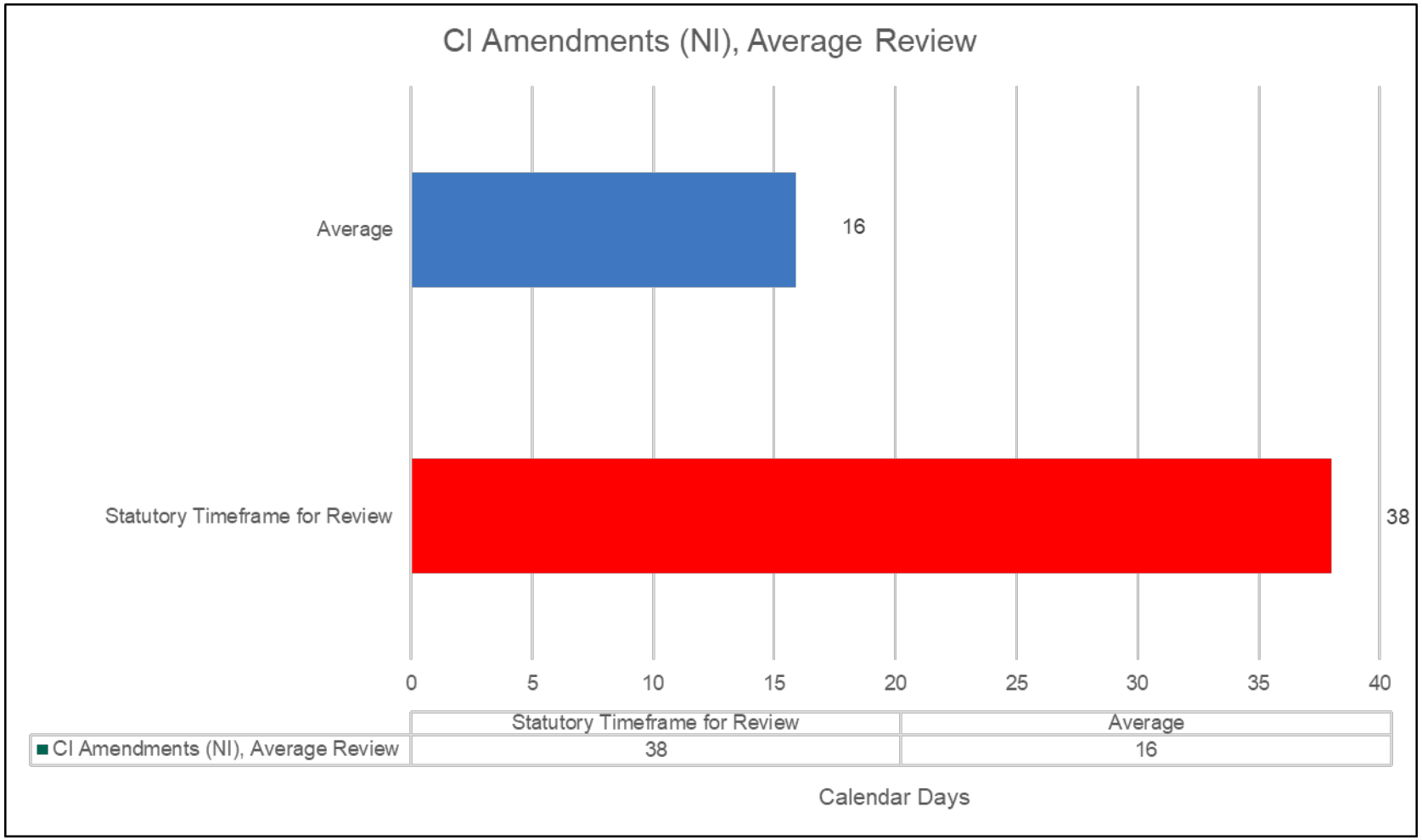
Figure 7. Average timeline (calendar days) for assessment of clinical investigation initial applications with expert assessors received from 1 May 2023 onwards for clinical studies carried out in NI: application review (from receipt of valid application to outcome issued (statutory timeframe for review 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 1 May 2023 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).

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