



Medicines & Healthcare products
Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

January – August 2023



Overview

Explanation of terms used

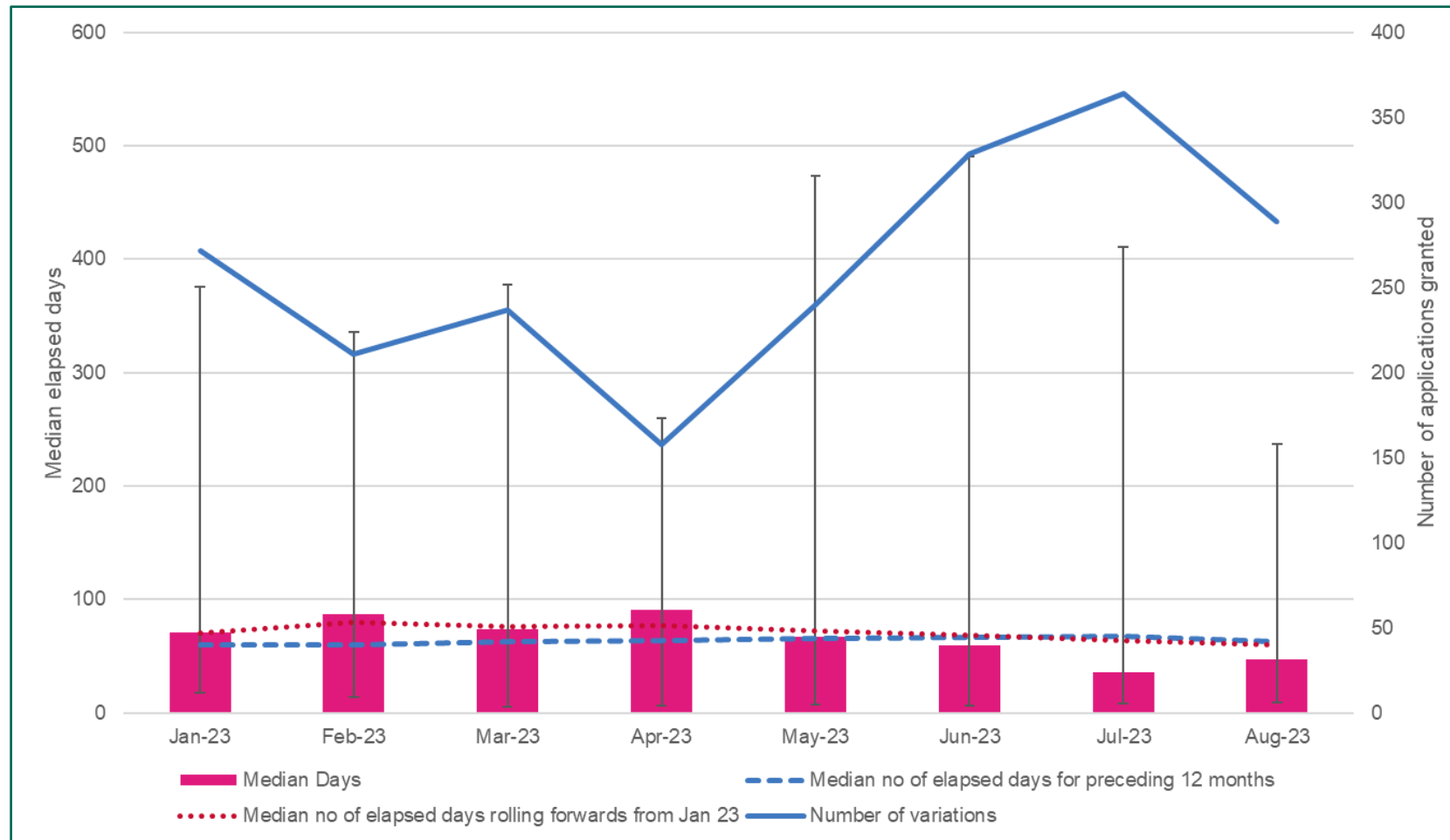
Terms used in slides

- Median elapsed days is calculated from date of validation to date of determination and is represented by the columns in the graphs. This is the total number of days between validation and determination (not clock on days).
- The error bars indicate the 10th (lower error bar) and 90th (upper error bar) percentiles and show the variability in the median elapsed days.
- Line extensions are included in the initials graph for established medicines.
- In some of the graphs the total median elapsed days for the preceding 12 months for each time point (month) on the graph is plotted as a line. For February 2023, for example, the line for the preceding 12 months will give the median elapsed days for January 2022 – January 2023, and for March 2023 the preceding 12 months will be February 2022 to February 2023, etc.
- In some of the graphs the accumulative median from January 2023 onwards at each time point (month) on the graph is plotted as a line. For January 2023, for example, the accumulative median from January 2023 would be the elapsed days for January 2023. For February 2023, the accumulative median would be the total elapsed days for January and February 2023, for March 2023, the accumulative median would be the total elapsed days for January, February and March 2023, etc.

Variations

Types IB and II

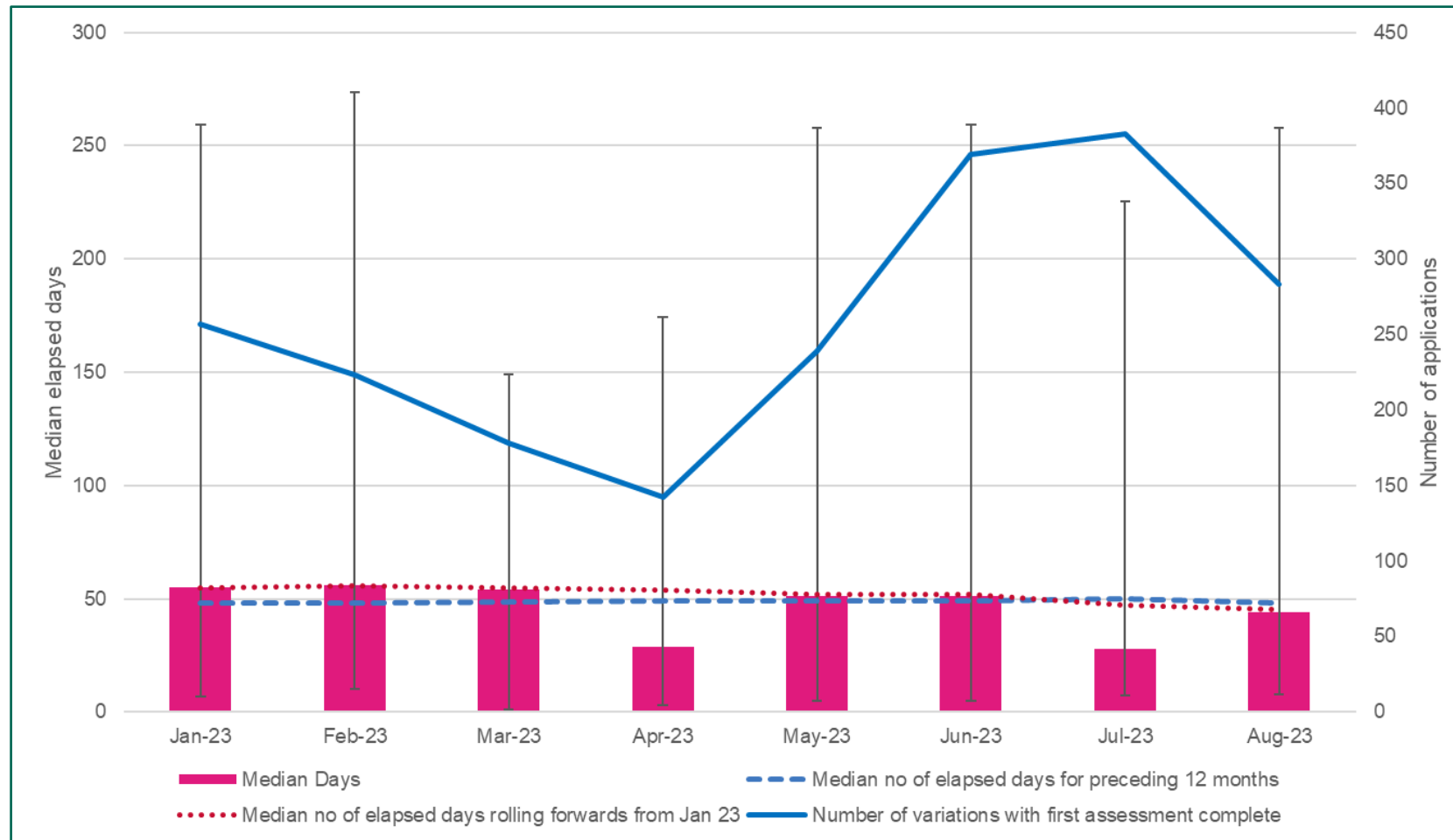
Figure 1. All variation type II procedures granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- This graph includes national, reliance and Project Orbis routes in median elapsed days for all for preceding 12 months.
- This graph shows lines for the median elapsed days for national, **reliance** and Project Orbis route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This graph includes all Type II variations managed by all areas of MHRA.

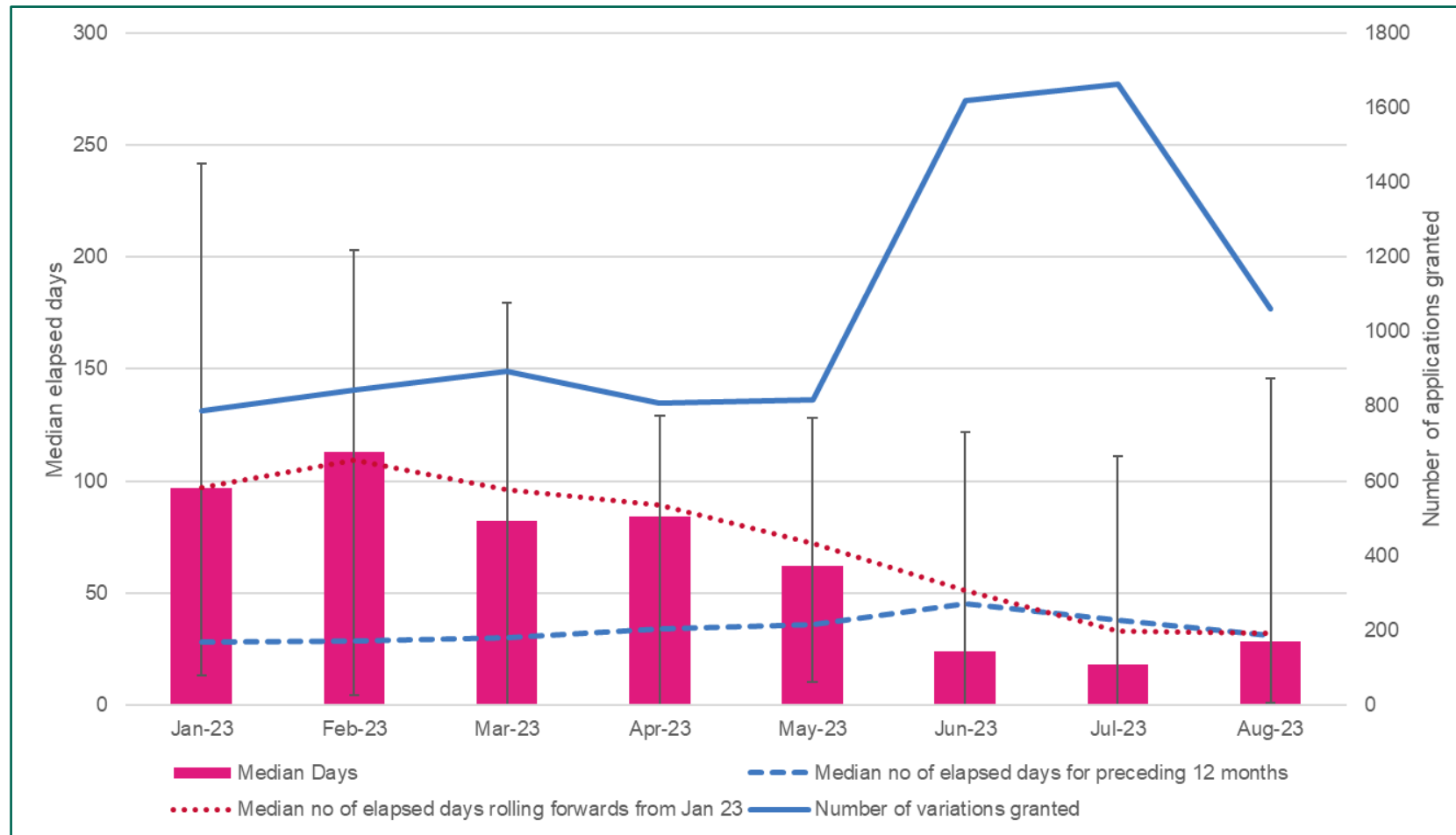
Figure 2. All variation type II procedures - median time to first assessment complete (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- This graph includes national, reliance and Project Orbis routes in median elapsed days for all for preceding 12 months.
- This graph shows lines for the median elapsed days for national, reliance and Project Orbis route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This graph includes all Type II variations managed by all areas of MHRA.

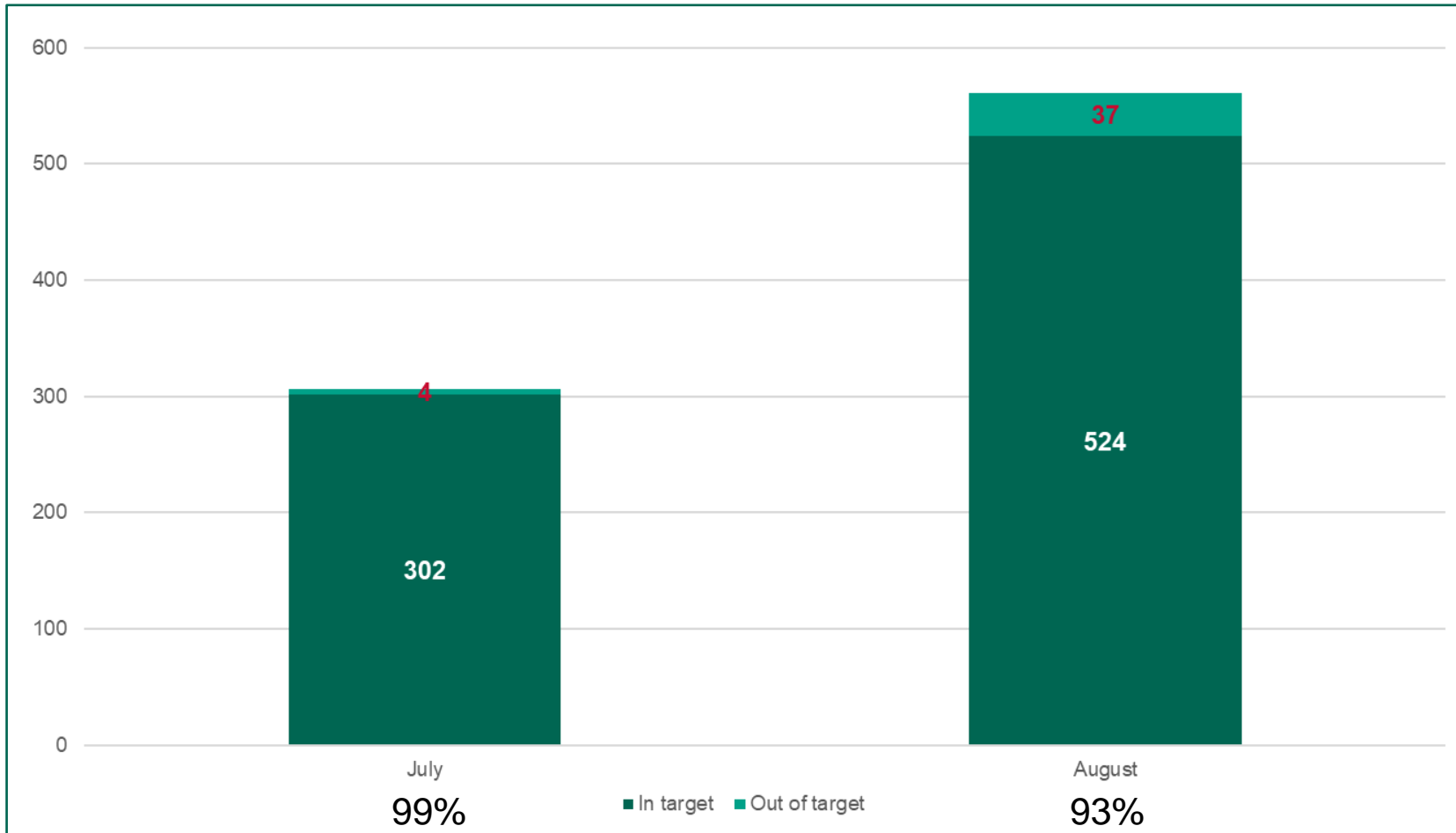
Figure 3. All variation type IB procedures granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- This graph includes national and reliance routes in median elapsed days for all for preceding 12 months.
- This graph shows lines for the median elapsed days for national and reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- End of March shows removal of Surge Resources to typical capability.
- This graph includes all Type IB variations managed by all areas of MHRA.

Figure 4. All variation type IB procedures granted



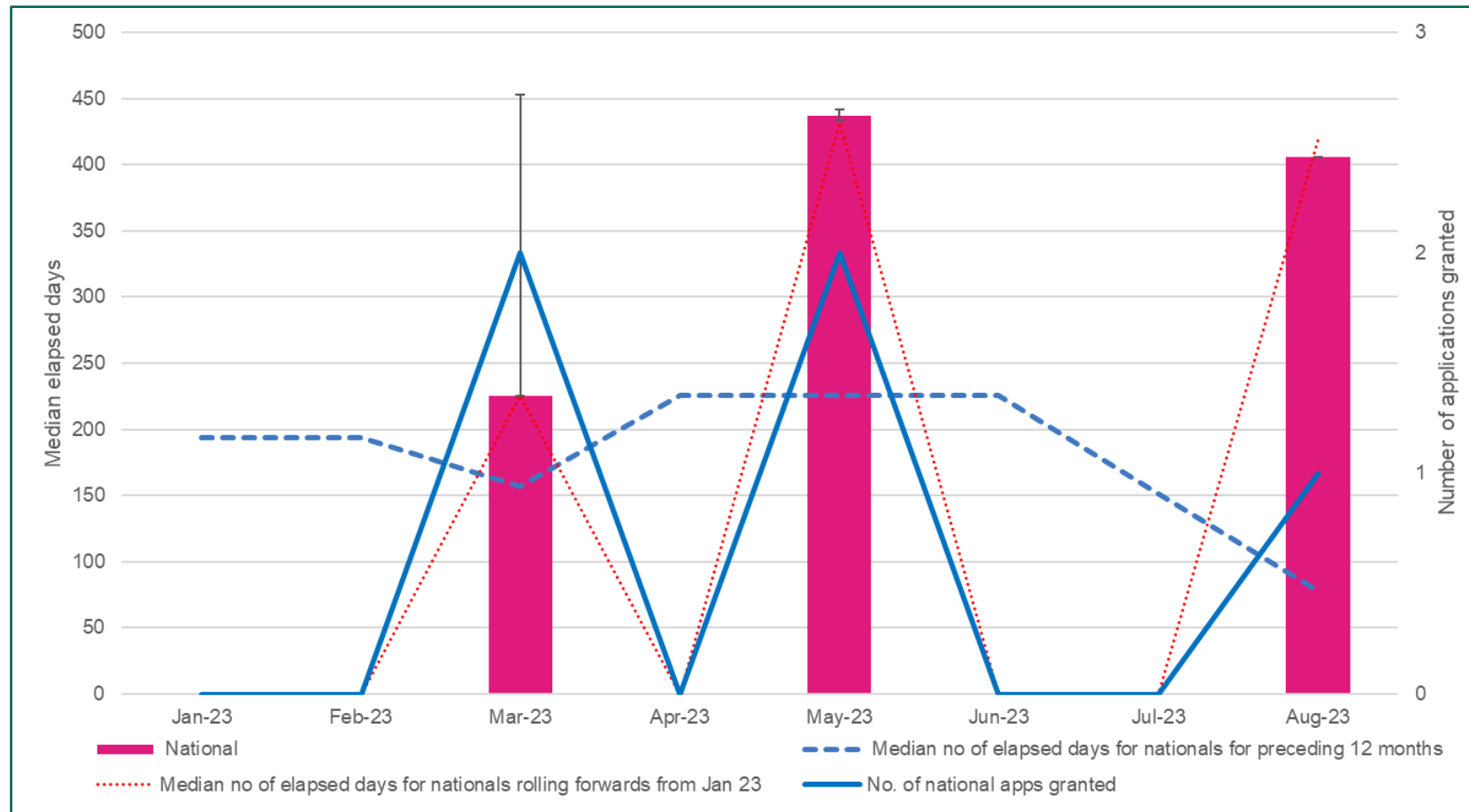
Key features

- This graph includes national and reliance routes
- This graph shows TIB variations received and validated from 1 July 2023 onwards.
- The number of applications granted for each month is also shown.
- This graph includes all Type IB variations managed by all areas of the MHRA.

NAS initials

Also includes Project Orbis,
The ACCESS Consortium
and first RFI

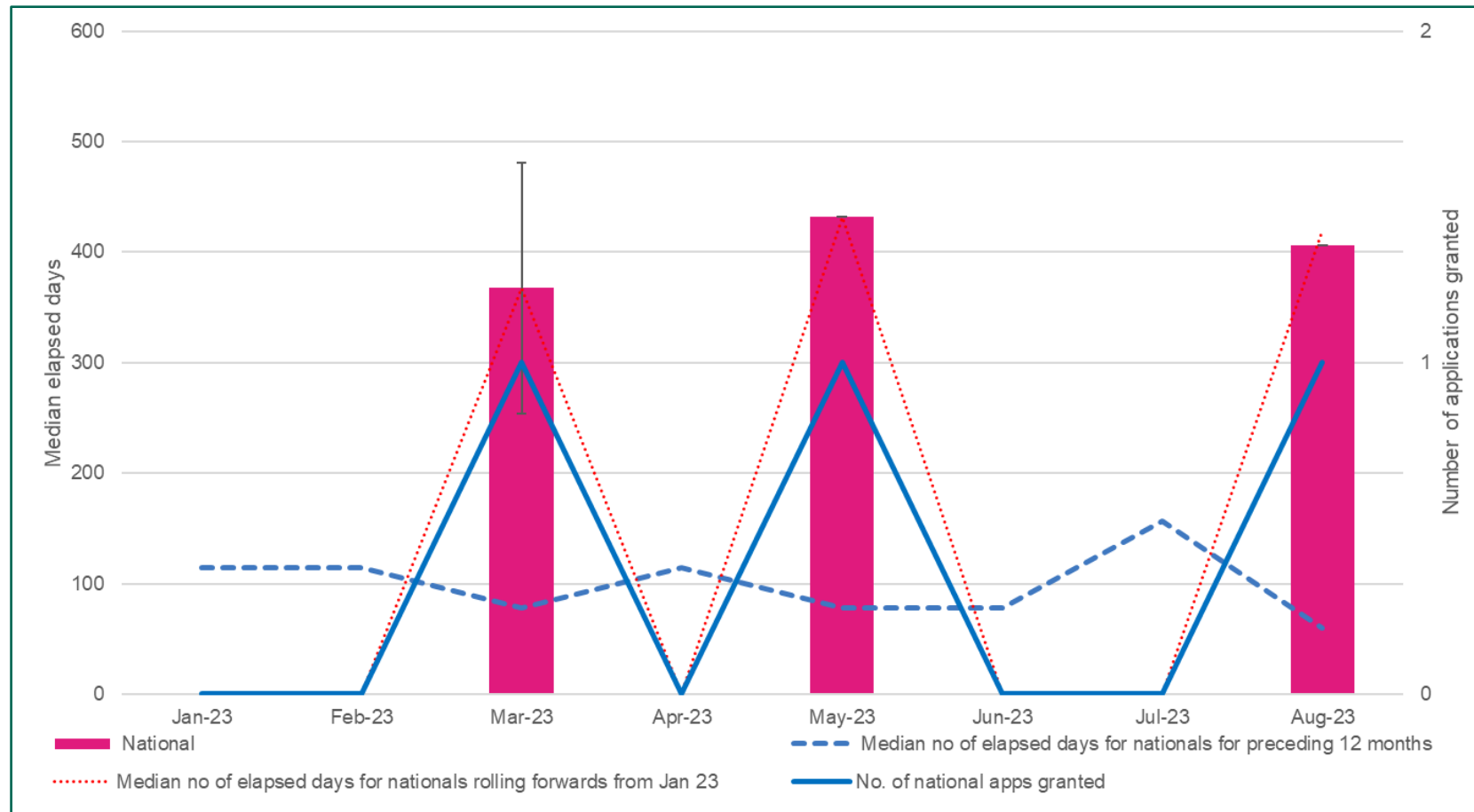
Figure 5. NAS national initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- This graph includes Project Orbis & The ACCESS Consortium in median elapsed days for nationals for preceding 12 months.
- This graph shows lines for the median elapsed days for national granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.

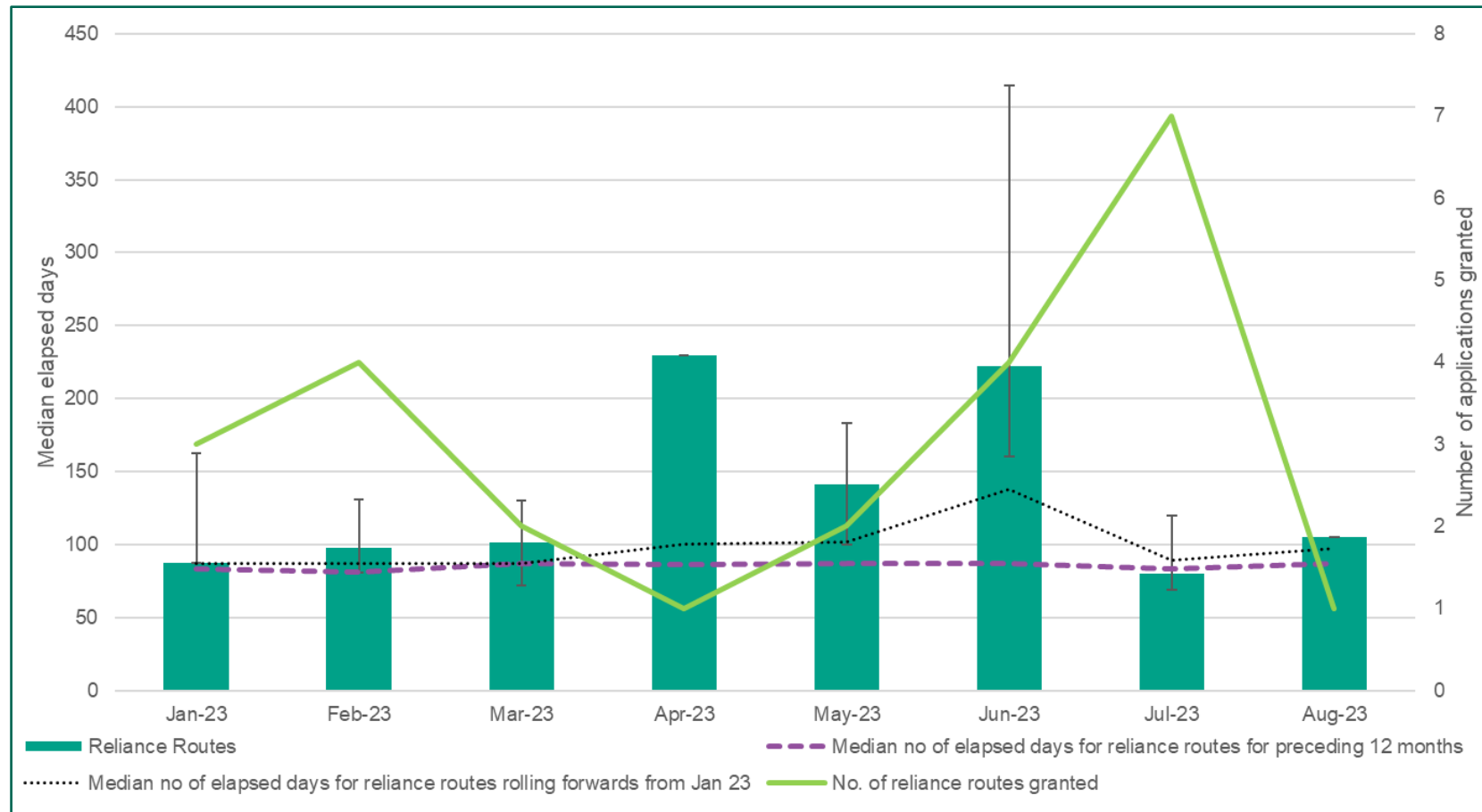
Figure 6. NAS national initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- This graph does not include Project Orbis & The ACCESS Consortium in national figures or median elapsed days for nationals for preceding 12 months.
- This graph shows lines for the median elapsed days for national granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.

Figure 7. NAS reliance initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, and median elapsed days for preceding 12 months



Key features

- Reliance routes include ECDRP and MRDC reliance.
- This graph shows lines for the median elapsed days for reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.

Figure 8. Project Orbis & The ACCESS Consortium initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023

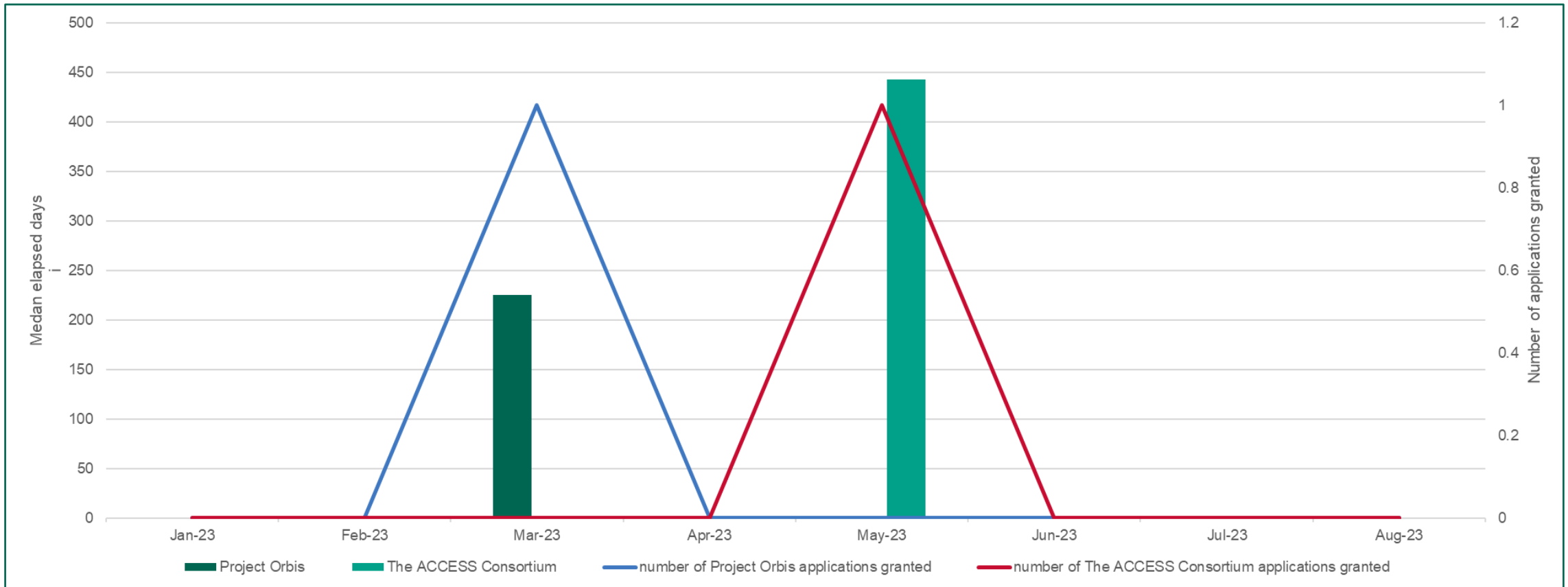
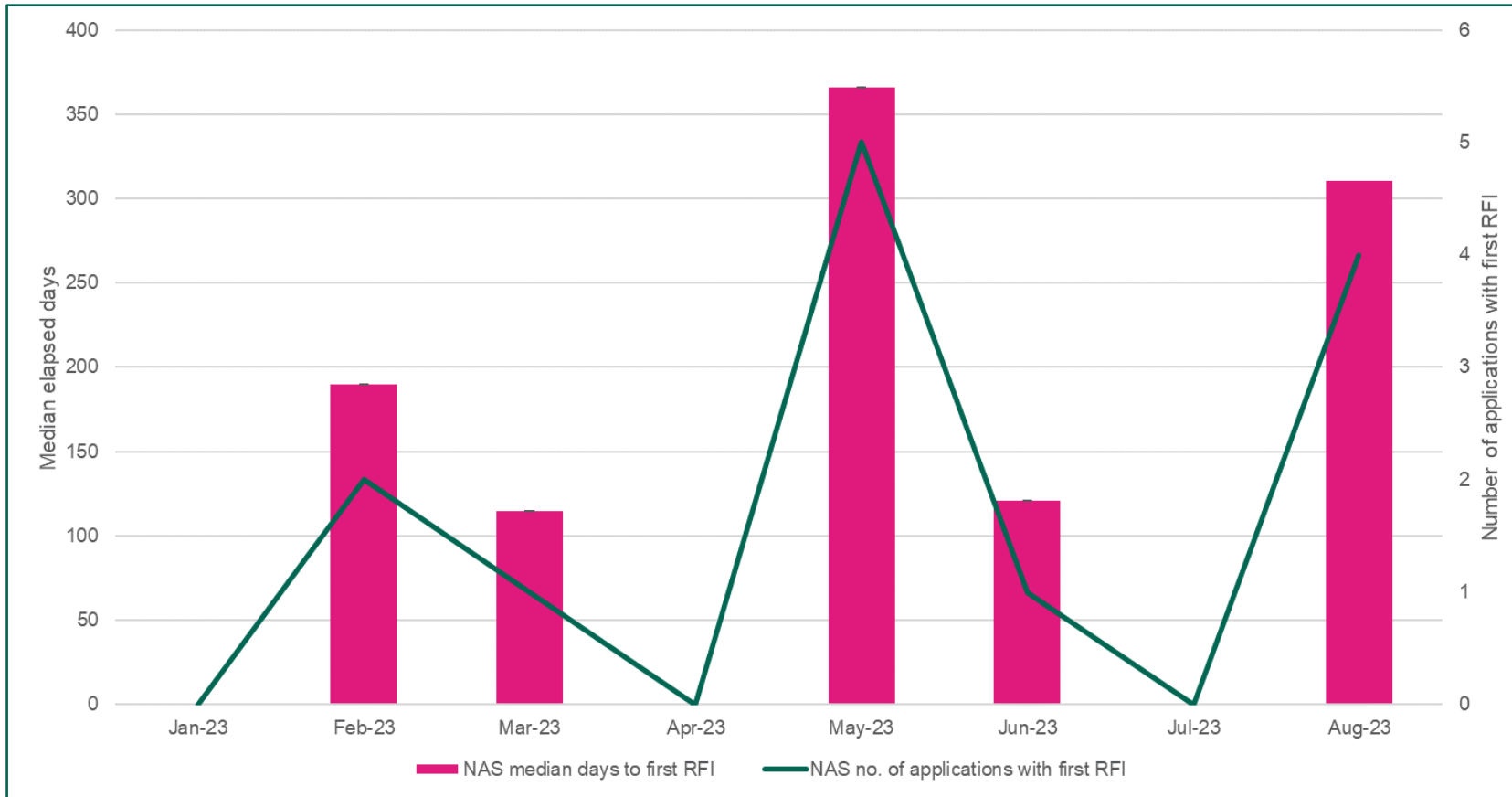


Figure 9. Initial national NAS licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan - August 2023



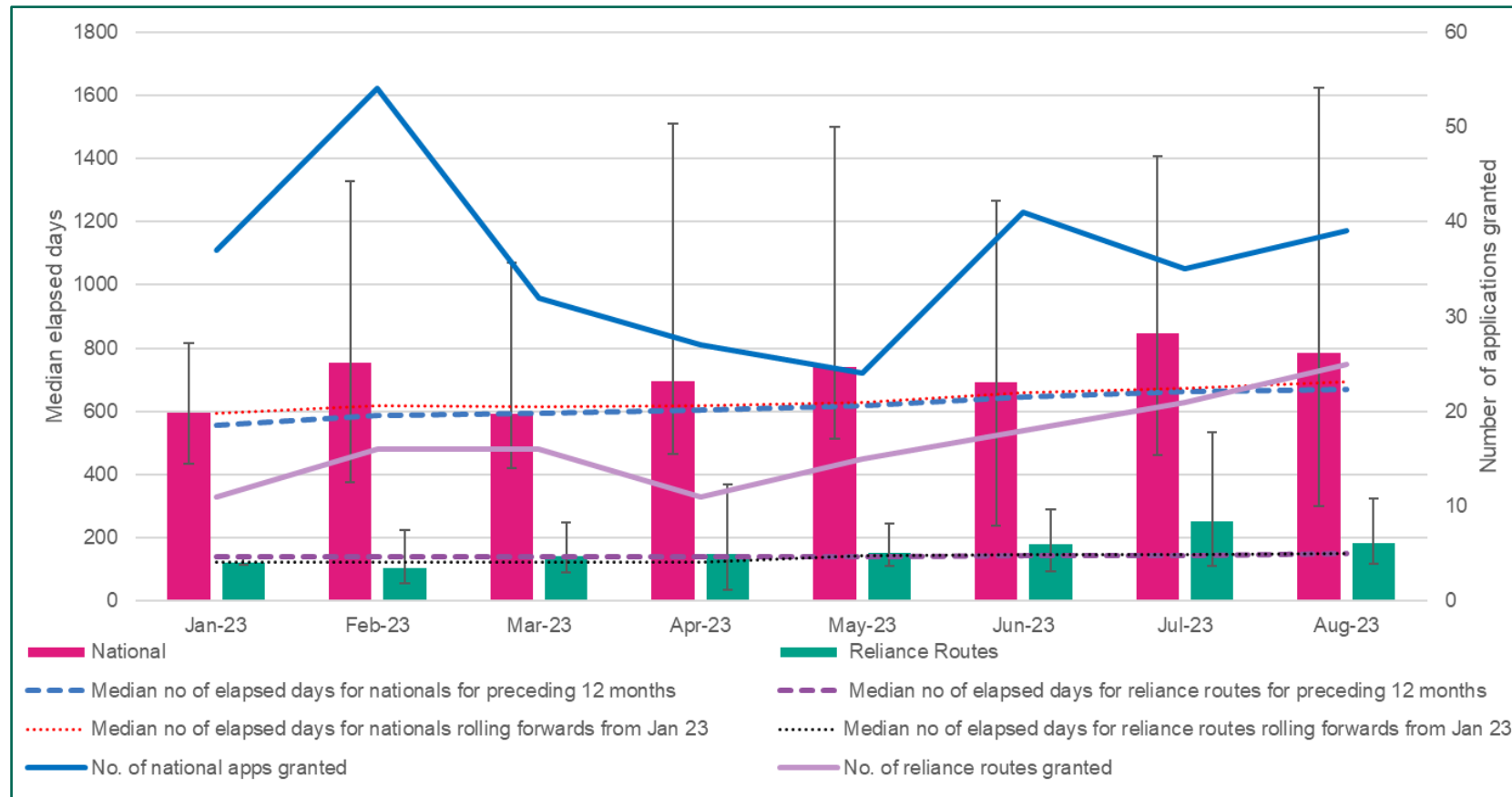
Key features

- This graph shows the median number of elapsed days from application received to first RFI.

Established medicines initials

Also includes first RFI

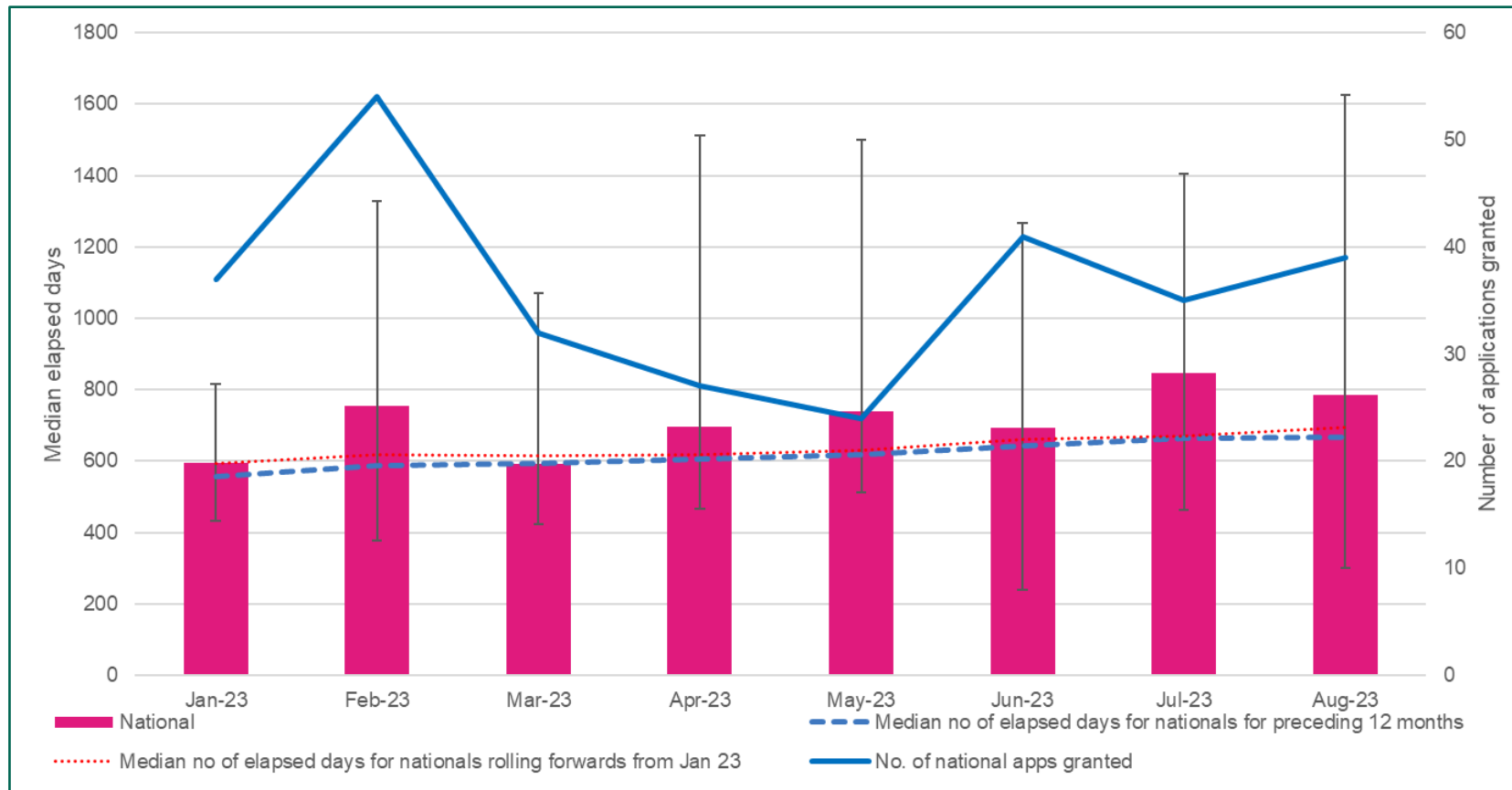
Figure 10. Established medicines initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- Reliance routes include ECDRP and MRDC reliance
- This graph shows lines for the median elapsed days for national and reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

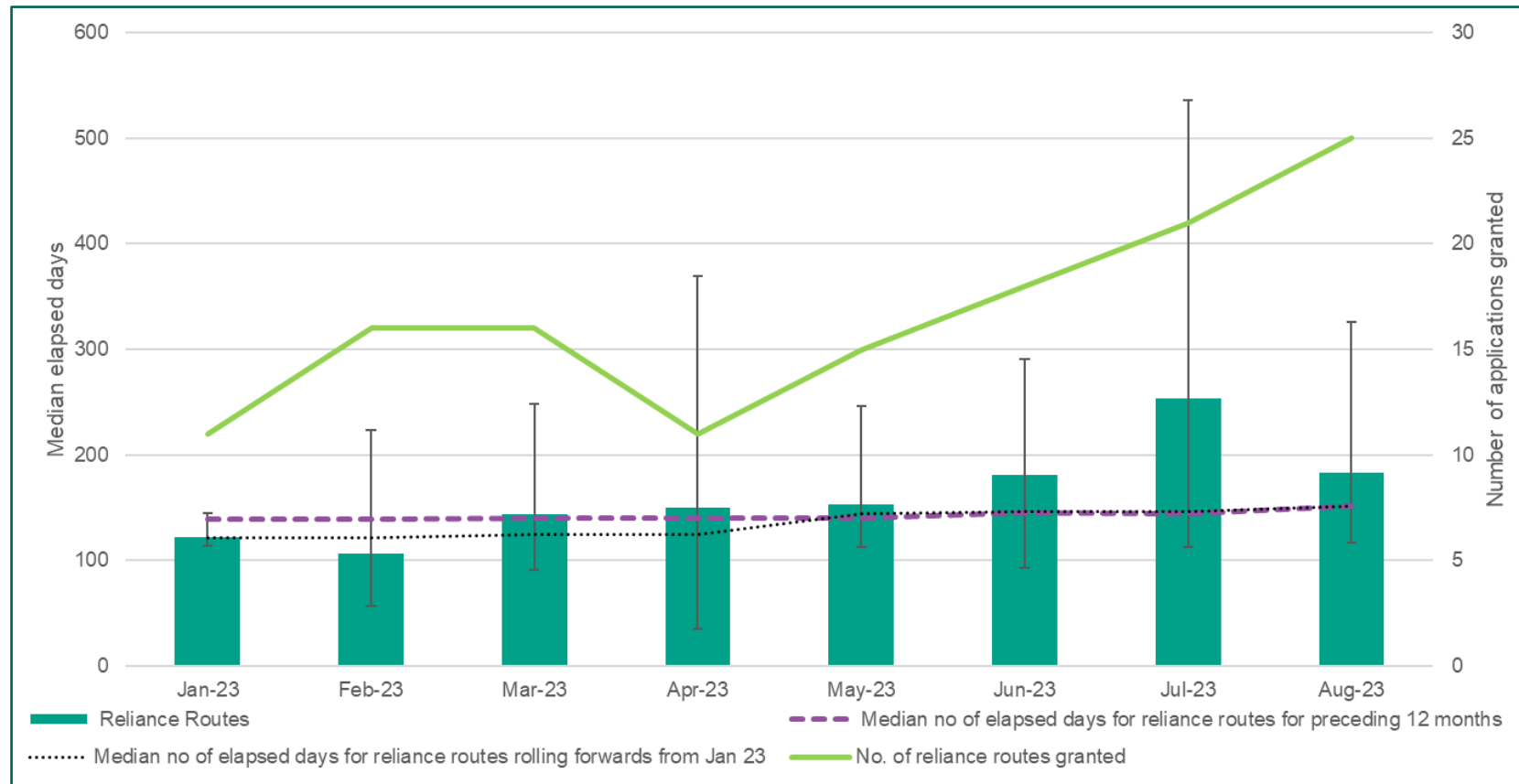
Figure 11. Established medicines national initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – August 2023, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- This graph shows lines for the median elapsed days for national granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

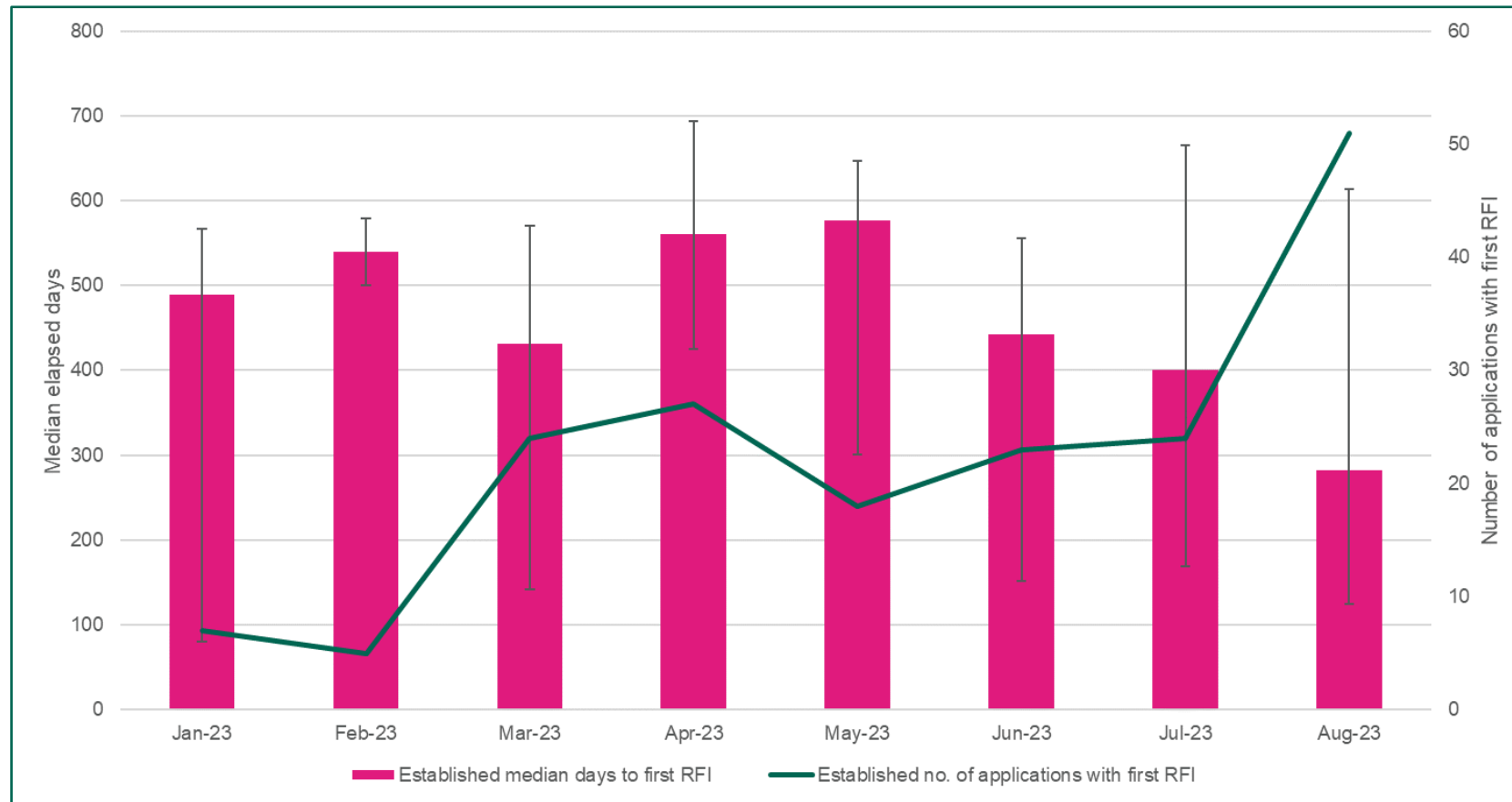
Figure 12. Established medicines reliance initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan –August 2023, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- Reliance routes include ECDRP and MRDC reliance
- This graph shows lines for the median elapsed days for reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

Figure 13. Initial national established licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan - August 2023



Key features

- This graph shows the median number of elapsed days from application received to first RFI.
- This includes applications which are being worked through from the queue, which is not truly able to be trended.

Variations metrics

National, ECDRP & MRDCP

Figure 14. Mean processing time, 50th and 90th percentile for New-MAA Mutual Recognition Reliance Procedure (MRDCRP) validation

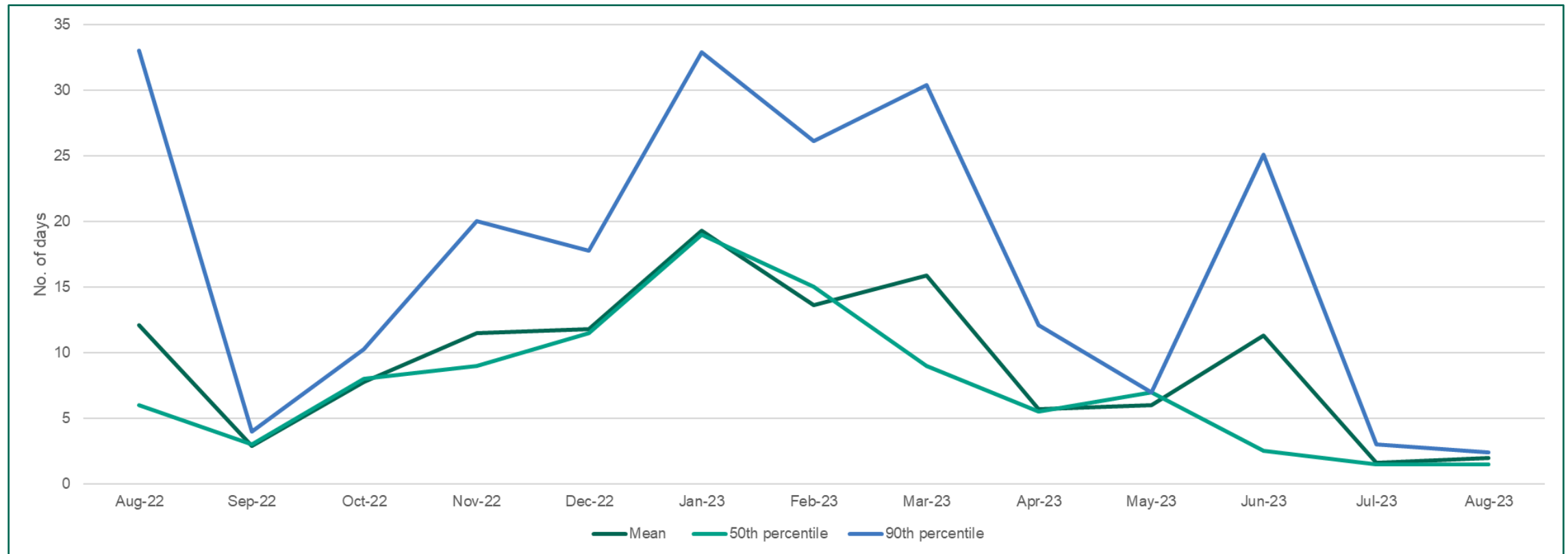


Figure 15. Mean processing time, 50th and 90th percentile for New-MAA National validation

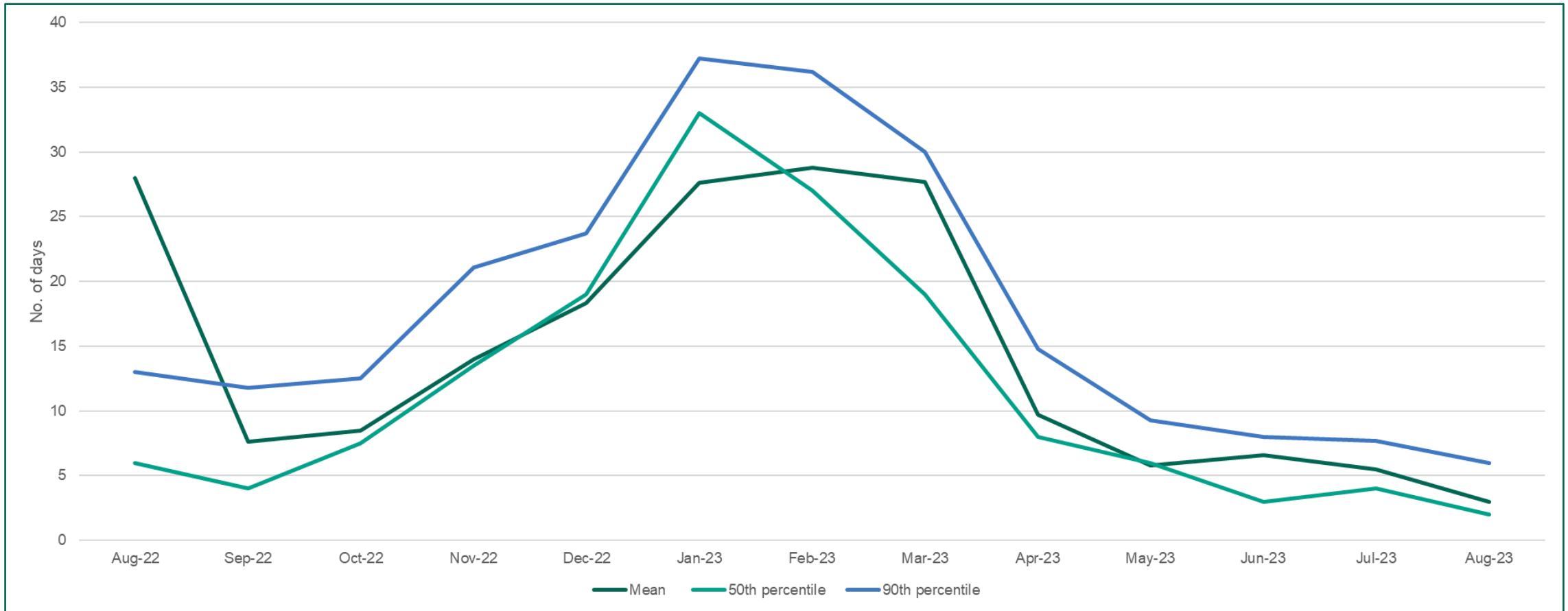
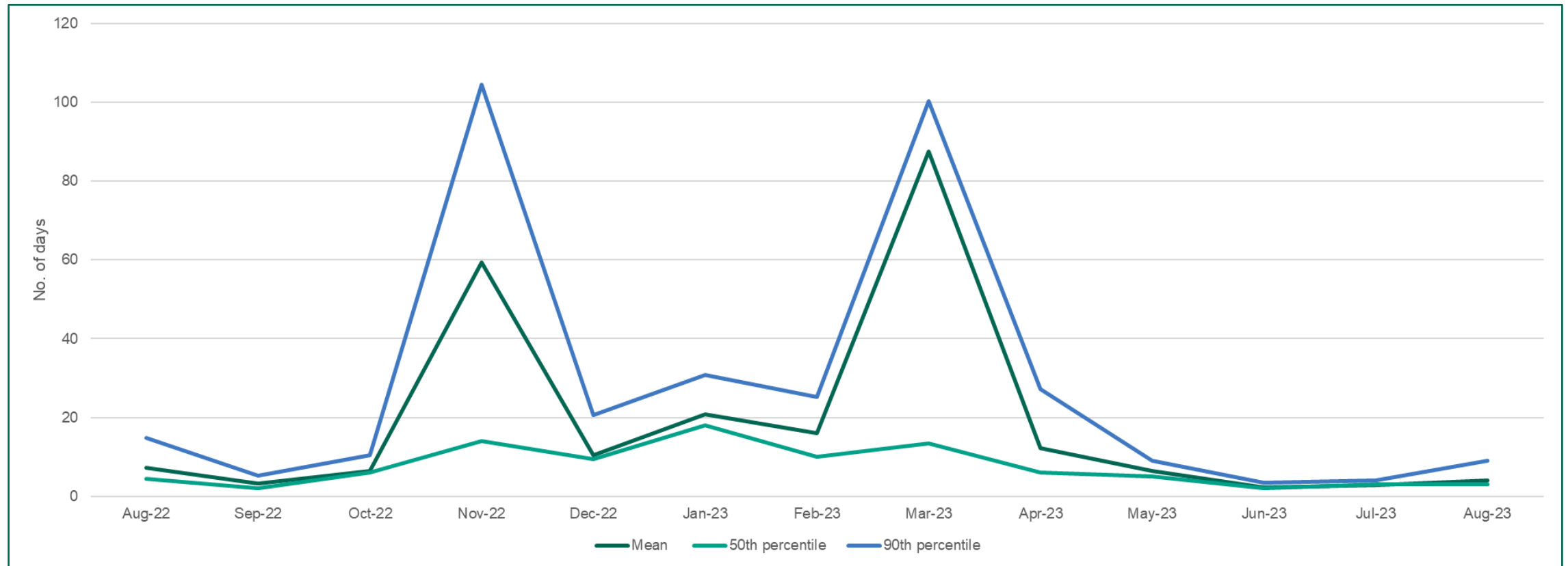


Figure 16. Mean processing time, 50th and 90th percentile for New-MAA Validation European Commission (EC) Decision Reliance Procedure (ECDRP)



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