Medicines & Healthcare products Regulatory Agency

MHRA Performance

Assessment of New Marketing
Authorisation Applications
and Variations

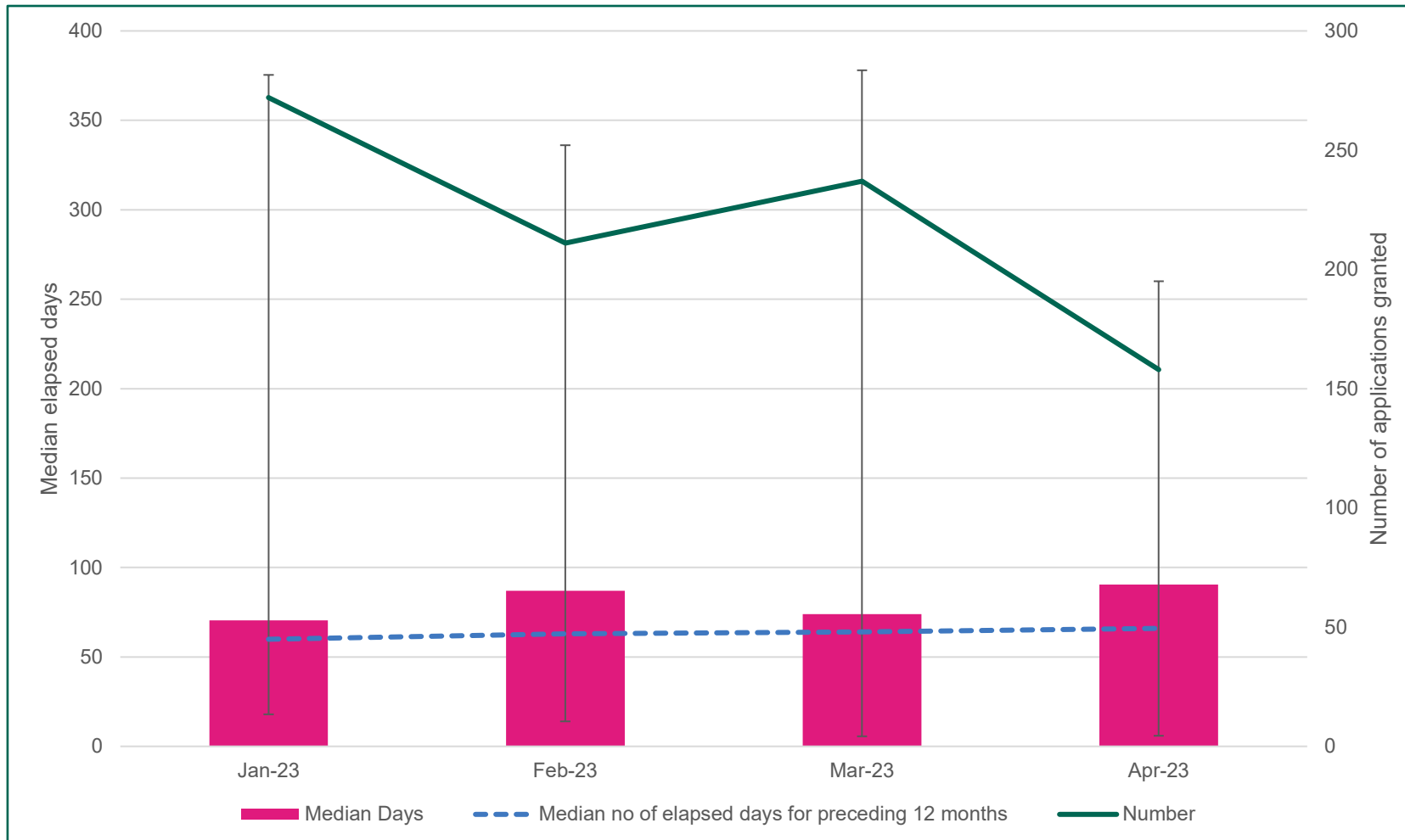**January 2023 – April 2023**

Overview

We have provided metrics for New Active Substance licences (Innovative medicines) and Established medicines licences, and variations managed by all areas of the MHRA as follows.

- Median number of elapsed days to determination from validation, median number of elapsed days to first assessment complete from validation, and median number of elapsed days to determination from validation, for all granted type II variations procedures (national, reliance, Project Orbis. Data for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards is also provided.

- Median number of elapsed days to determination from validation for NAS granted initial licences for national and reliance routes both including and not including Project Orbis and The ACCESS Consortium data. Data for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards and number of applications granted is also provided.

- Median number of elapsed days to determination from validation and number of applications granted for Project Orbis and The ACCESS Consortium.

- Median number of elapsed days to determination from validation for established medicines granted initial licences for national and reliance routes. Data for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards and number of applications granted is also provided.

- The median number of elapsed days from application received to first RFI and number of applications with first RFI for both NAS and established medicines.
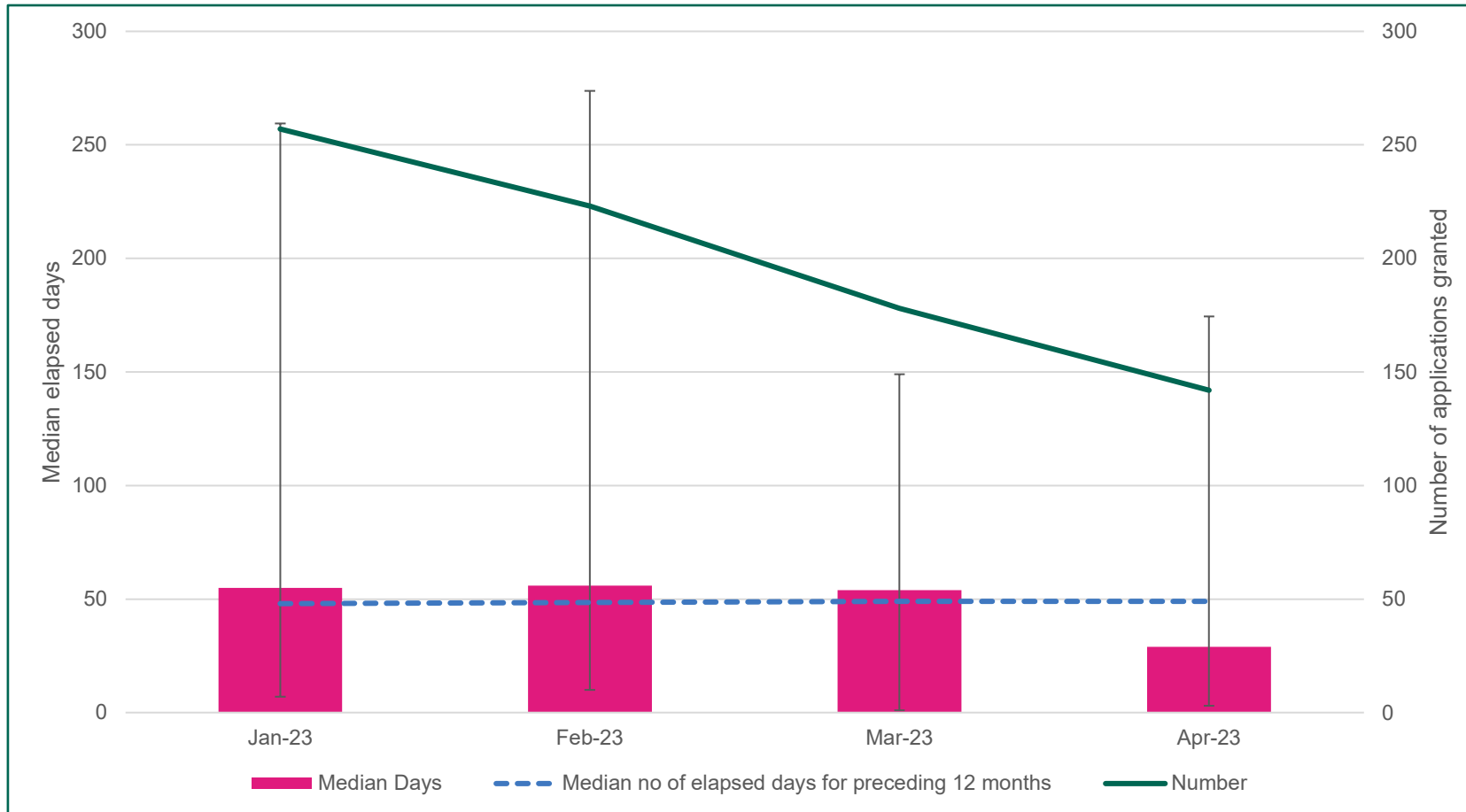
Variations

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 – Apr 2023, and median elapsed days for preceding 12 months

Key features

- Figure 1 includes national, reliance and Project Orbis routes in median elapsed days for all for preceding 12 months.

- Figure 1 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.

- Figure 1 includes all Type II variations managed by all areas of MHRA.
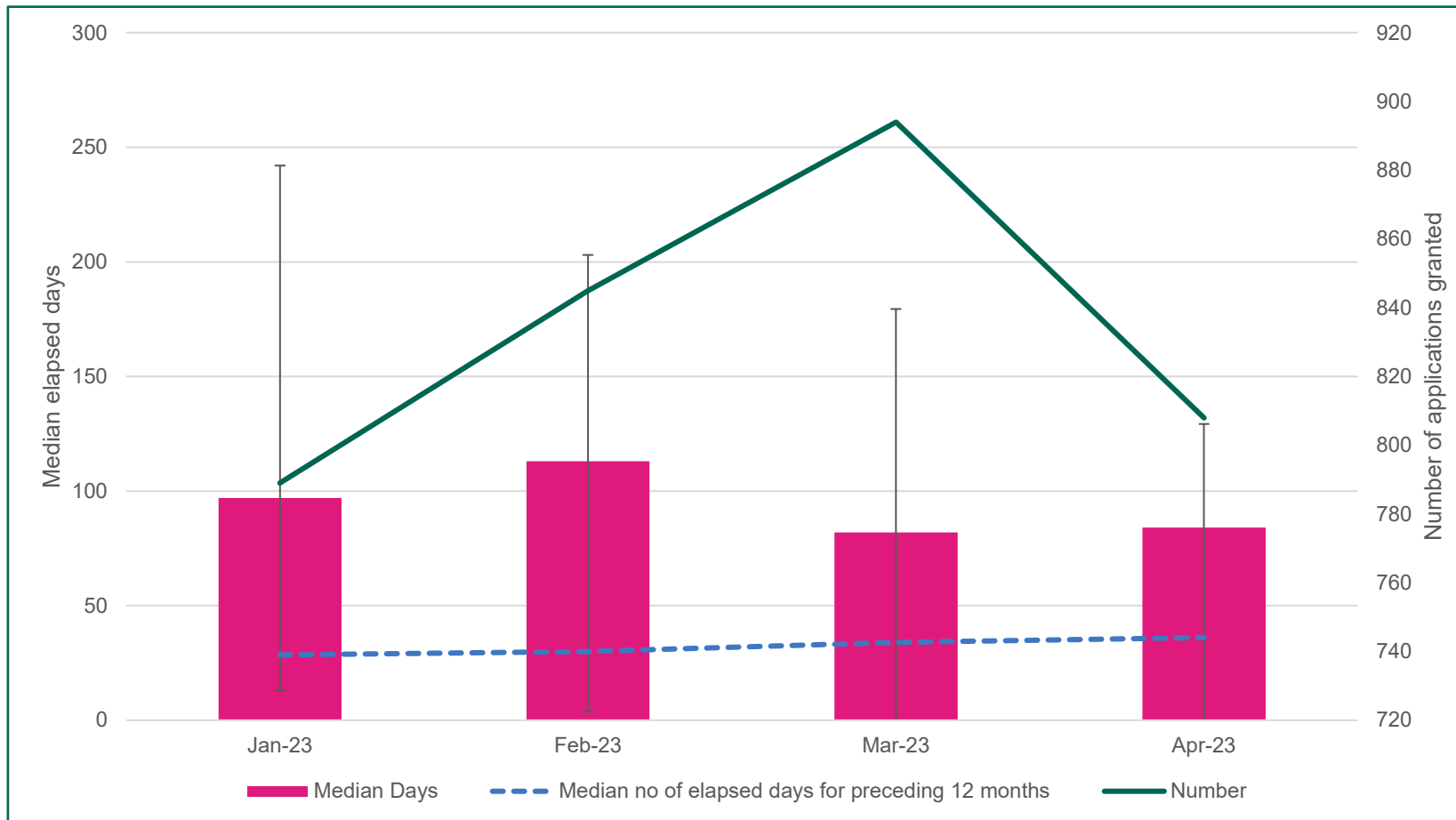
Figure 2. All variation type II procedures - median time to first assessment complete (total elapsed days since validation) & number of applications for Jan – Apr 2023, and median elapsed days for preceding 12 months

Key features

- Figure 2 includes national, reliance and Project Orbis routes in median elapsed days for all for preceding 12 months.

- Figure 2 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.

- Figure 2 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 – Apr 2023, and median elapsed days for preceding 12 months
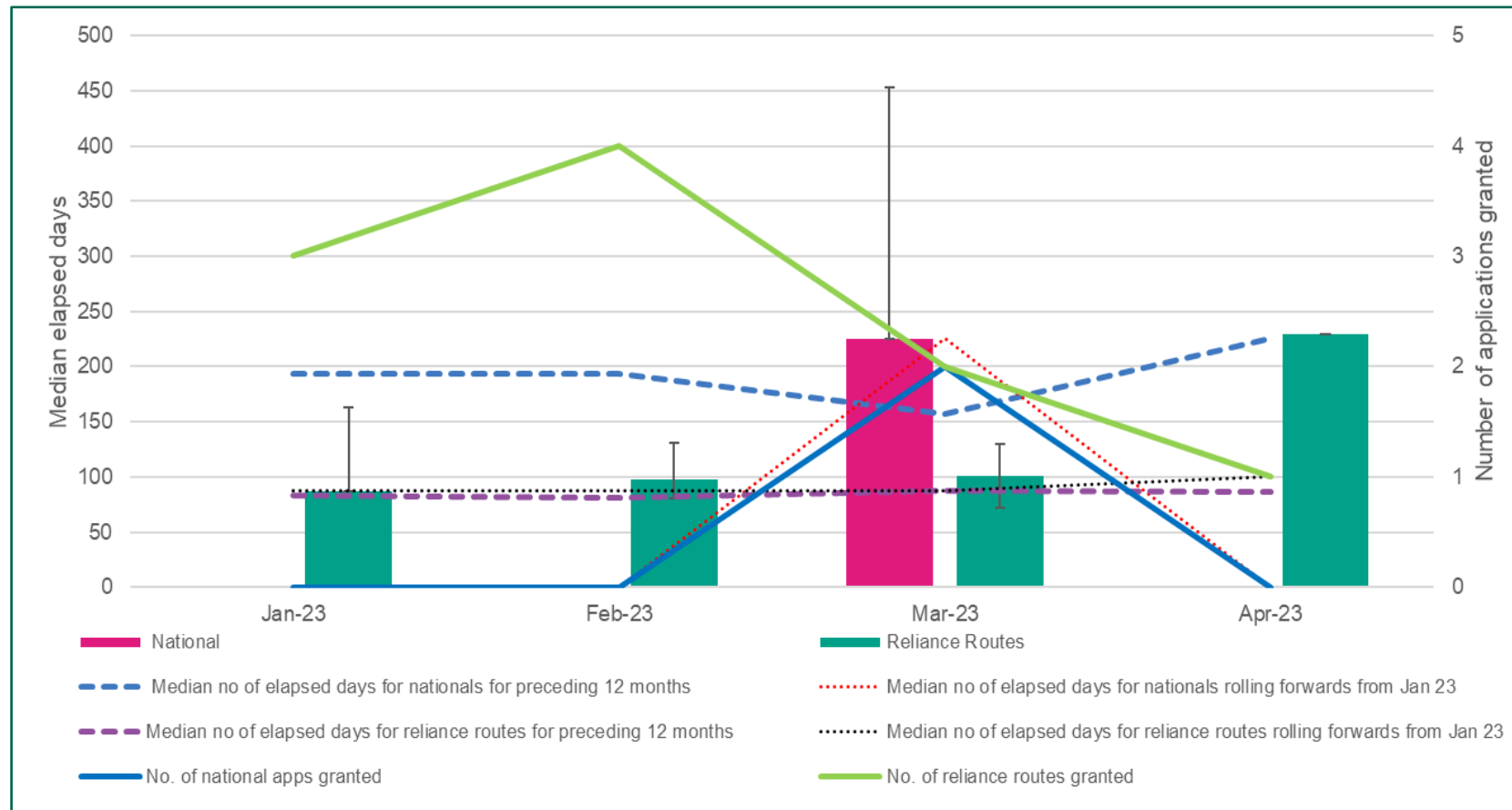

Key features

- Figure 3 includes national and reliance routes in median elapsed days for all for preceding 12 months.
- Figure 3 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.
- Figure 3 includes all Type IB variations managed by all areas of MHRA.

NAS initials

Also includes Project Orbis,
the ACCESS Consortium and first RFI

Figure 4. NAS initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – Apr 2023, and median elapsed days for preceding 12 months
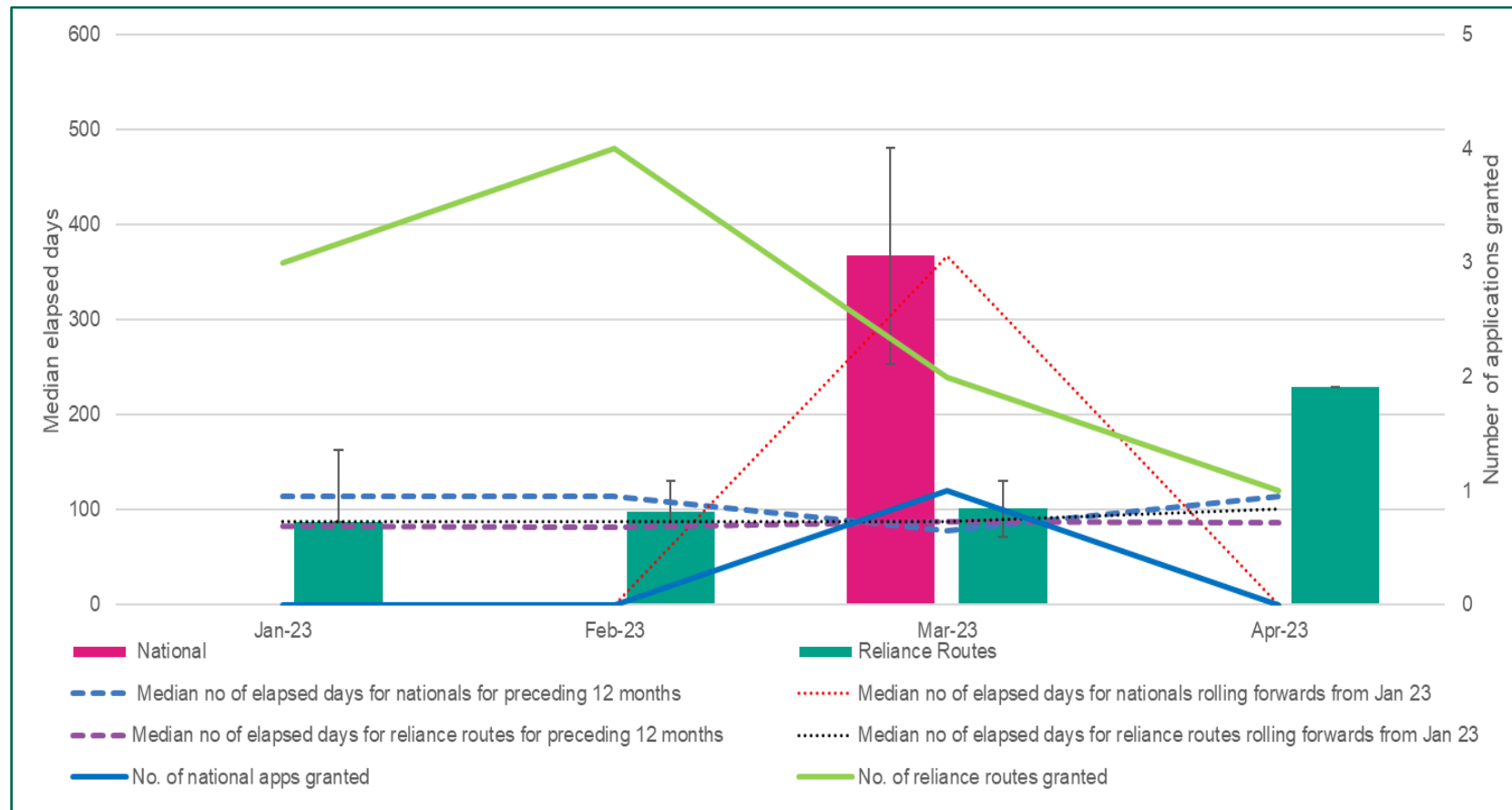

Key features

- Reliance routes include ECDRP and MRDC reliance.

- Figure 4. includes Project Orbis & The ACCESS Consortium in median elapsed days for nationals for preceding 12 months.

- Figure 4 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.
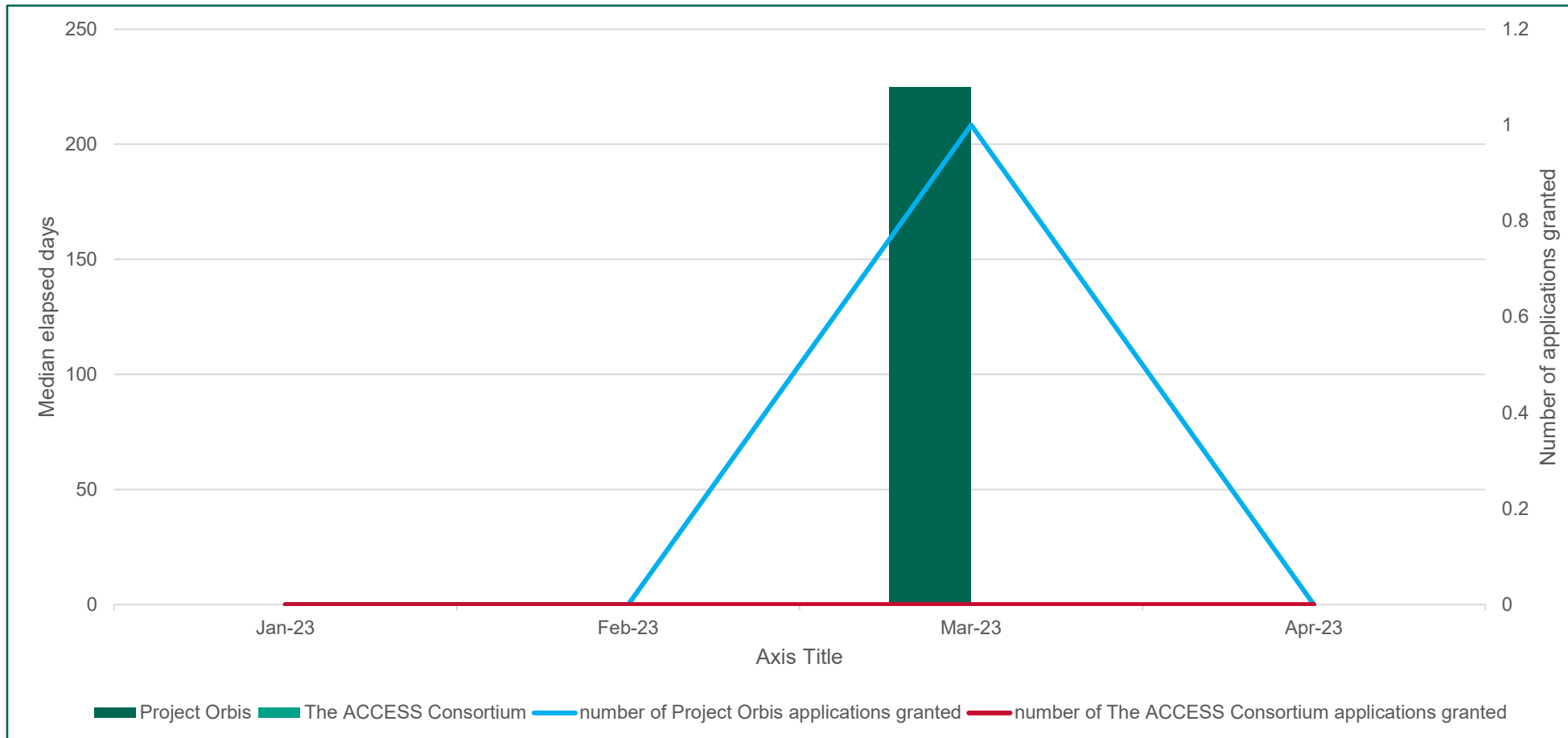
Figure 5. NAS initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – Apr 2023, and median elapsed days for preceding 12 months
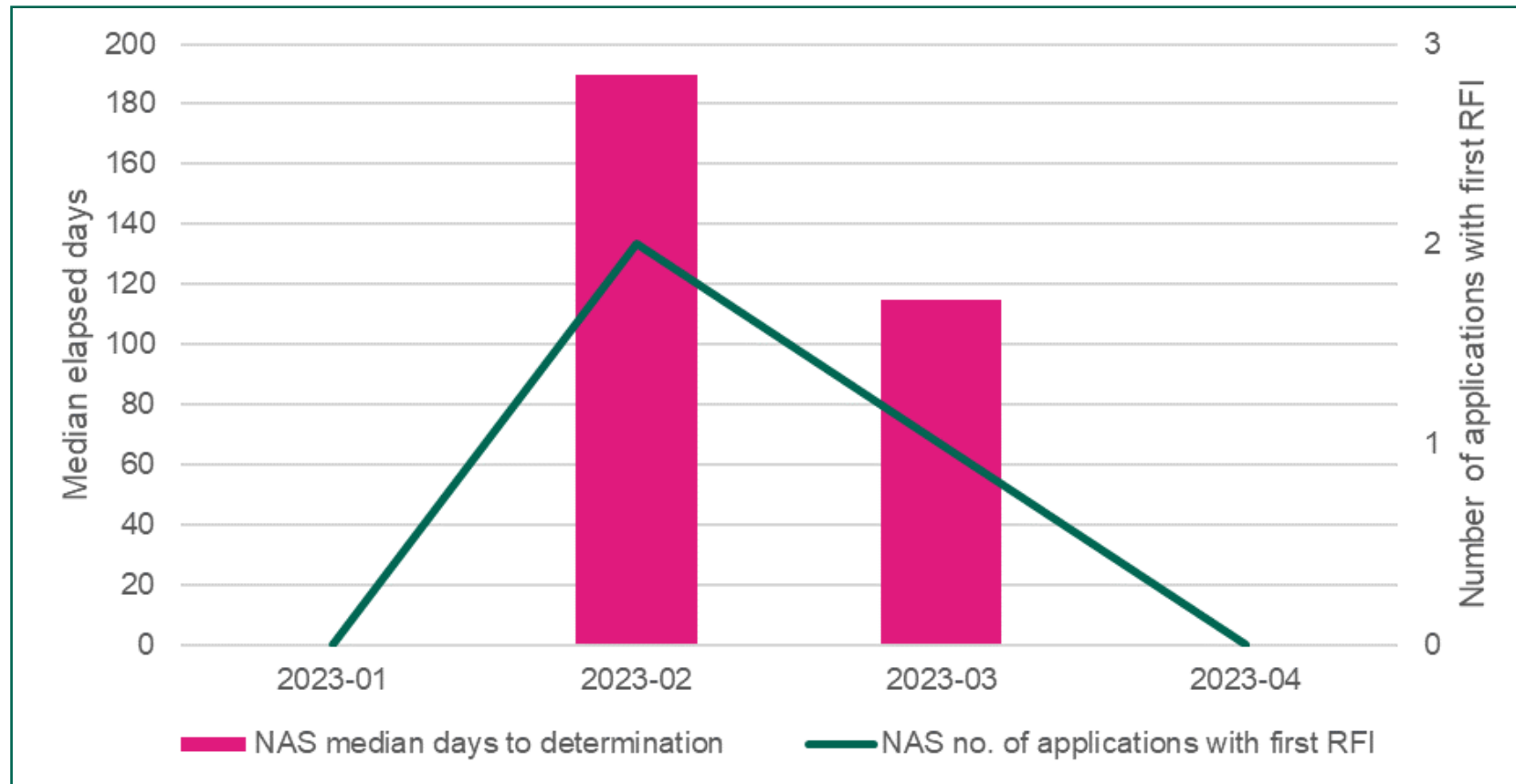

Key features

- Reliance routes include ECDRP and MRDC reliance.

- Figure 5 does not include Project Orbis & The ACCESS Consortium in national figures or median elapsed days for nationals for preceding 12 months.

- Figure 5 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.

Figure 6. Project Orbis & The ACCESS Consortium initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – Apr 2023

Figure 7. Initial national NAS licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan - Apr 2023
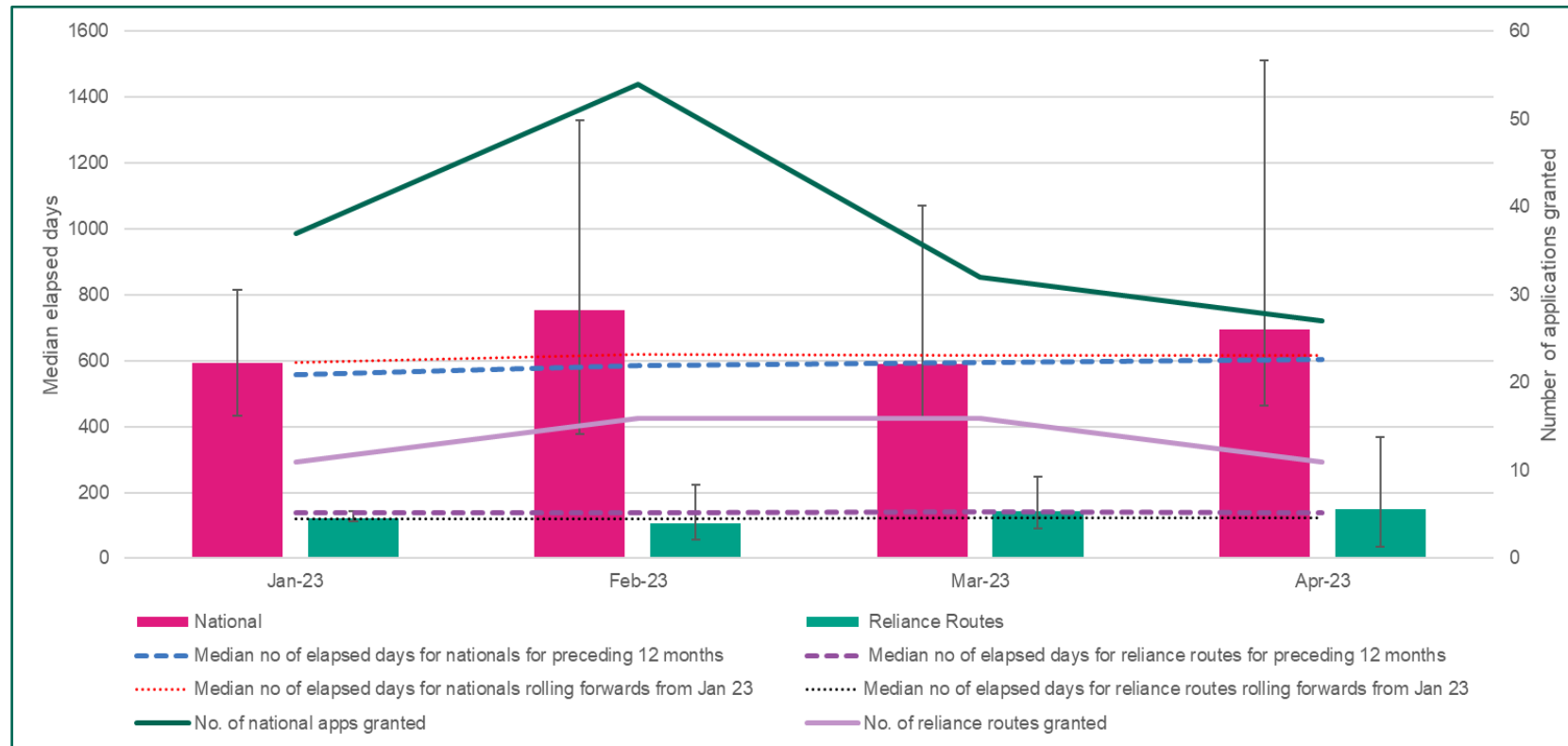

Key features

- Figure 7 shows the median number of elapsed days from application received to first RFI.

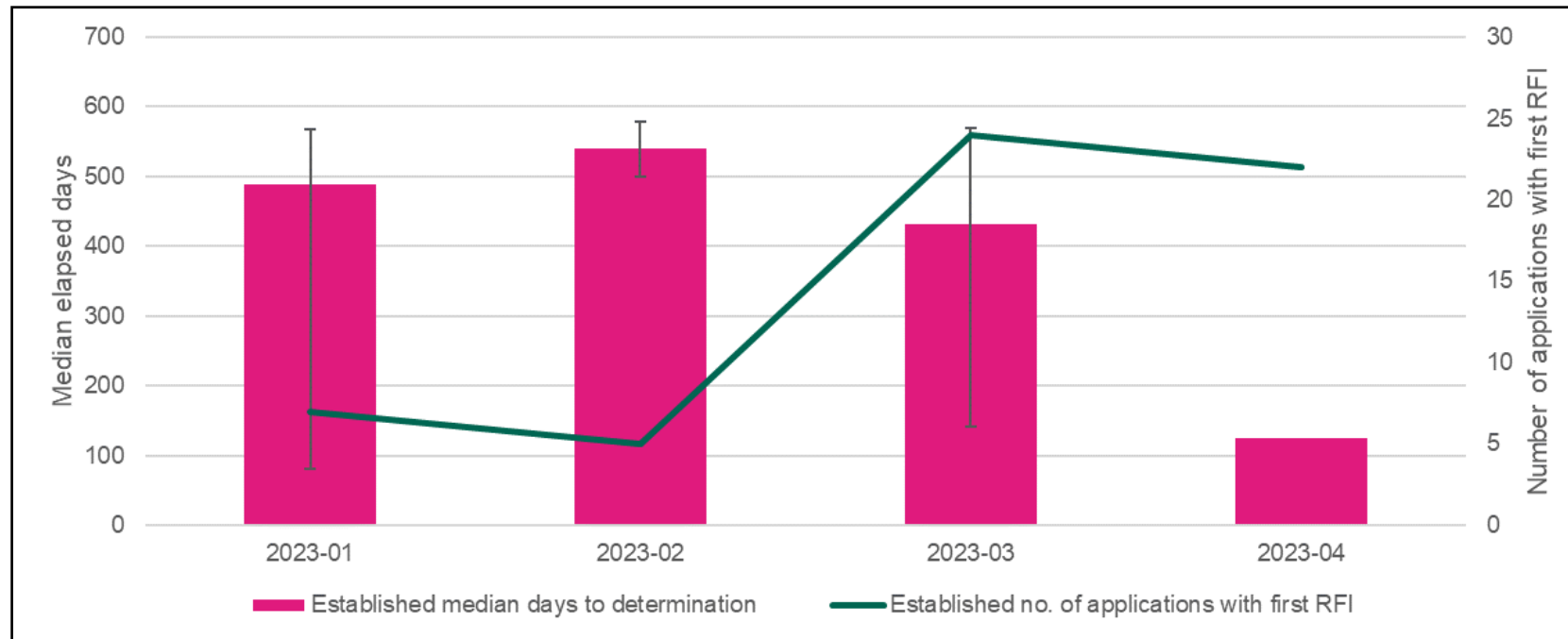# Established medicines initials

Also includes first RFI

Figure 8. Established medicines initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan – Apr 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

- Figure 8. 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 9. Initial national established licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan - Apr 2023

Key features

- Figure 9 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.

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