NICE National Institute for Health and Care Excellence

HPR207

How Long Is Long Enough? Data Collection Duration for Medicines in Managed Access in England

Bee C[1], Austin C[1], Wakefield L[1], Williamson S[1]

[1] National Institute for Health and Care Excellence

Background

Managed access agreements (MAAs) are a form of Managed Entry Agreement (MEA) used in England. MAAs are funded by NHS England through the Cancer Drugs Fund[1] (CDF) and Innovative Medicines Fund[2] (IMF). The duration of data collection specified in the data collection arrangement (DCA) for an MAA is the designated minimum period, up to a maximum of five years, to resolve key uncertainties and optimise the chance of routine commissioning at re-evaluation. Data specified in a DCA may include clinical trial data, real-world clinical practice data (RWD), or a combination of the two.

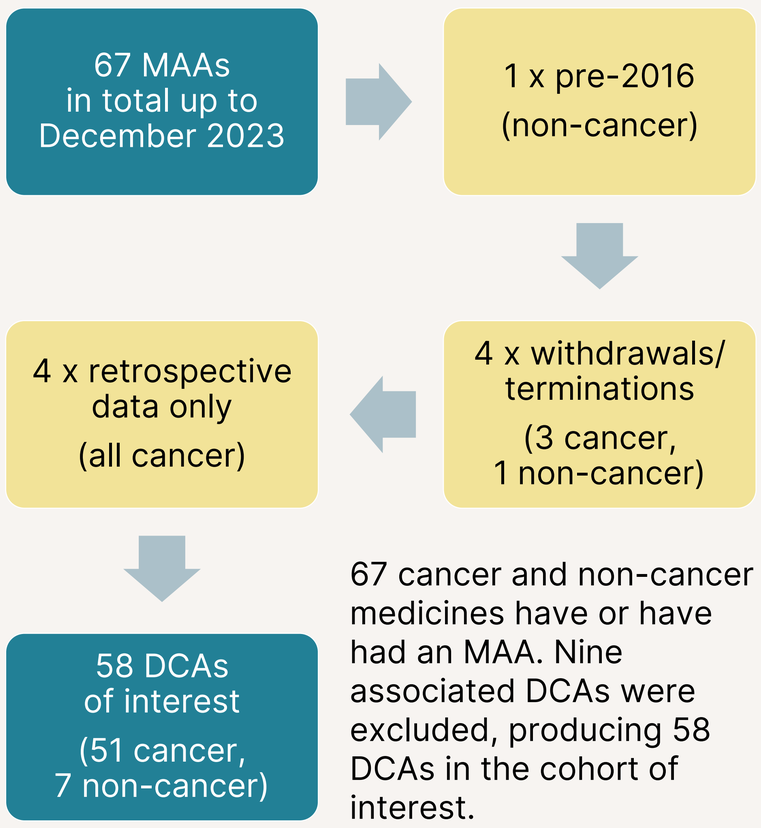
What we did and why

We reviewed the duration of prospective data collection for MAAs in England. We extracted start and end dates of prospective data collection for medicines that entered MAAs in England from January 2016 to December 2023. Exclusion criteria were applied, and data sources characterised for analysis.

The aim was to identify trends associated with the data collection duration required for an MAA and the type or maturity of the RWD or clinical trial data.

A total of 67 treatments were identified as having or having had an MAA published by NICE. Both cancer and non-cancer medicines were included. Nine DCAs associated with the MAAs were excluded either because the publication date was out of scope, guidance had been withdrawn before the end of the MAA, or because data collection was retrospective rather than prospective.

Figure 1: Derivation of DCAs of interest from all MAAs



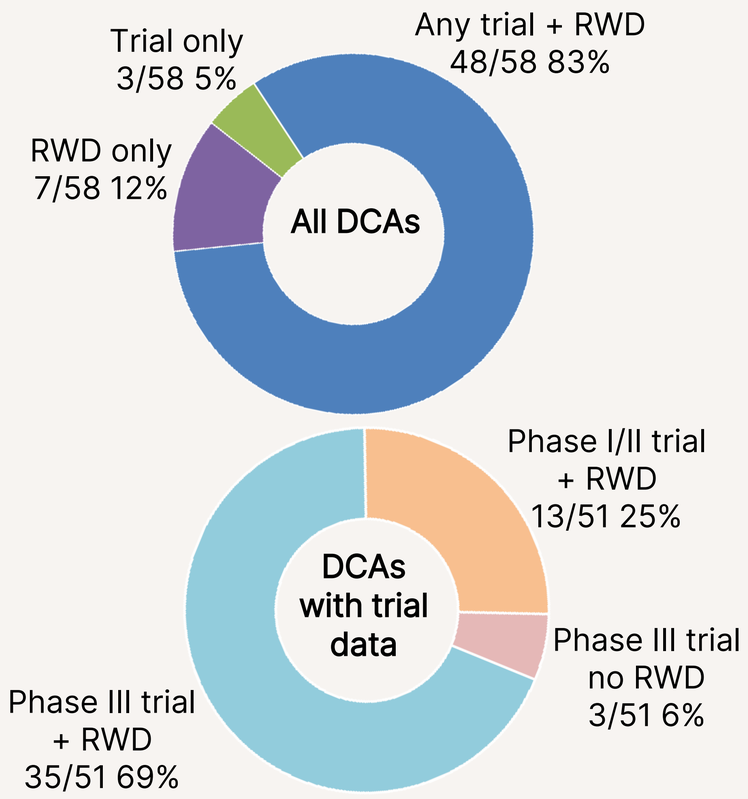
67 cancer and non-cancer medicines have or have had an MAA. Nine associated DCAs were excluded, producing 58 DCAs in the cohort of interest.

Outcomes and impact

For the 58 DCAs of interest, median data collection duration was 2.16 years, with range less than 1 year to more than 5 years.

Median data collection duration of all DCAs is 2.16 years.

Figure 2: Breakdown of data sources in DCAs of interest



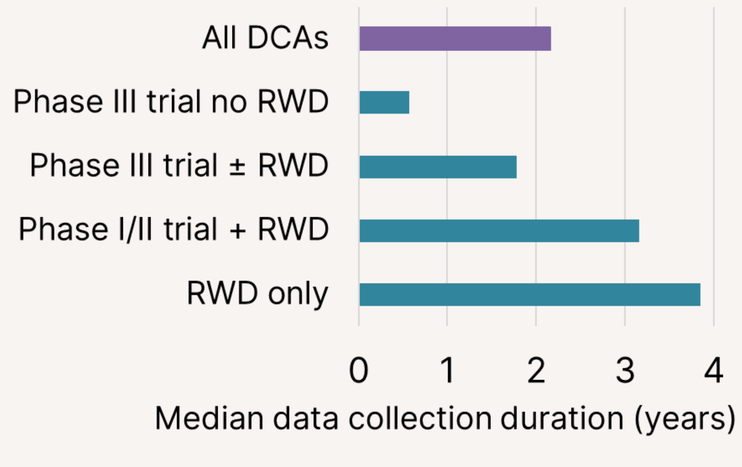
Most DCAs (48/58, 83%) specified both trial and real-world data (RWD), median duration was 1.99 years. A further 12% (7/58) specified RWD only, median duration was 3.85 years. The remaining 5% (3/58) specified Phase III trial data only, median duration was 0.57 years. Three quarters of DCAs (38/51, 75%) specifying trial data with or without RWD, included later cut-off data from ongoing Phase III trials, median duration was 1.78 years. The remaining quarter (13/51, 25%) specified Phase I or II trial data with RWD, median duration was 3.16 years.

What we learnt

There is a correlation between later phase trials with or without RWD and shorter duration of data collection. Treatments where earlier phase trials with RWD or RWD alone were specified to resolve key uncertainties required longer data collection.

Later phase trials with or without RWD have shorter data collection durations in managed access

Figure 3: Median data collection duration in years by type of data specified in DCAs of interest



Earlier licensing by regulators may affect future data collection duration for managed access

Conclusion

As regulators consider less mature data for licensing purposes, we may expect treatments recommended into managed access to require longer agreements, up to the current maximum data collection duration of five years.

References

1. NHS England (2016) Appraisal and funding of cancer drugs from July 2016. Accessed 21/10/24
2. NHS England (2021) NHS England » Innovative Medicines Fund. Accessed 21/10/24

Charlotte Bee, PhD
Programme Manager – Data Projects
National Institute for Health and Care Excellence
Email: managed.access@nice.org.uk