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Treatment Continuation With Cladribine Tablets Beyond Year 4: Analysis of Longitudinal Prescription Data From Germany

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RESEARCH IN CONTEXT

Most PwMS in a real-world setting who received two annual, short-course treatments with cladribine tablets in Years 1 and 2 were neither prescribed further treatment with cladribine tablets beyond the 4-year treatment period nor switched to another DMT.

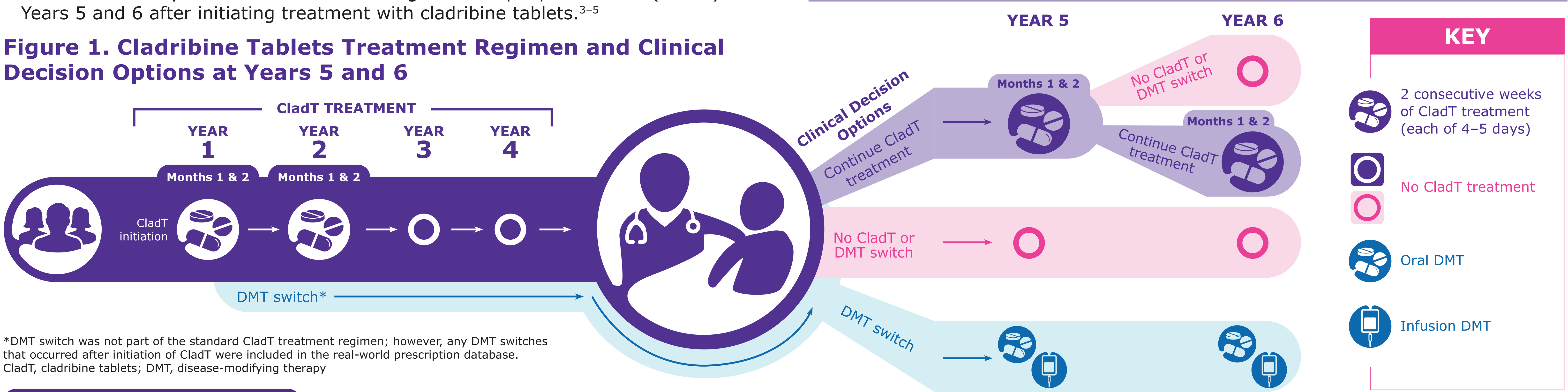
INTRODUCTION

- Cladribine tablets are effective in the treatment of relapsing multiple sclerosis (MS) and have a treatment regimen of two annual active treatment courses in Years 1 and 2 with no additional planned treatment in Years 3 and 4 (**Figure 1**).[1,2]
- There are few reports on the clinical management of people with MS (PwMS) in Years 5 and 6 after initiating treatment with cladribine tablets.[3–5]

OBJECTIVE

To describe the treatment patterns and characteristics of PwMS in Germany who reached Years 5 and 6 after initiating treatment with cladribine tablets.

Figure 1. Cladribine Tablets Treatment Regimen and Clinical Decision Options at Years 5 and 6



*DMT switch was not part of the standard CladT treatment regimen; however, any DMT switches that occurred after initiation of CladT were included in the real-world prescription database.
CladT, cladribine tablets; DMT, disease-modifying therapy

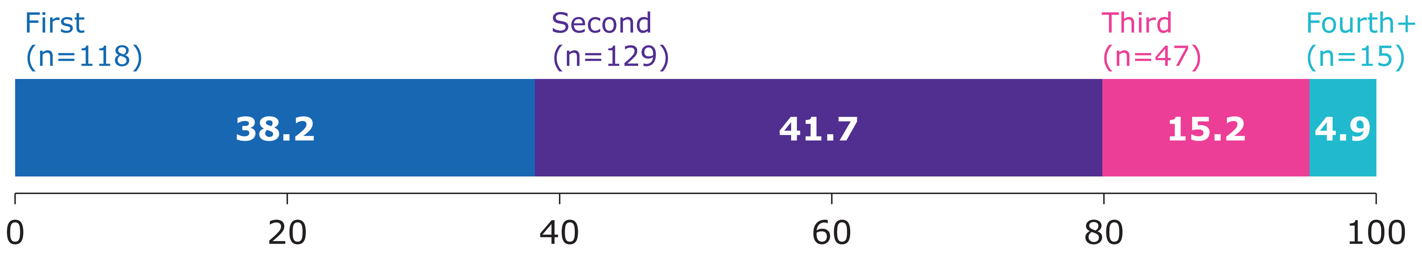
METHODS

- This retrospective analysis of the IQVIA longitudinal prescription (LRx) database of prescription information in Germany included PwMS who initiated treatment with cladribine tablets between September 2017 and December 2018.
  - The observation period was from the first cladribine tablets prescription until the end of Year 5 or Year 6 with at least an additional 6 months of follow-up.
  - Two panels within the dataset were used: the Trust Centre Panel that used projected data and served to identify the treatment patterns after initiation of treatment with cladribine tablets, and the Long-term Panel that served to analyse prescriptions prior to initiation of cladribine tablets. The latter did not include projected data.
- Details of the study design, including the projection factors, are shown in the **Supplementary Methods** and **Supplementary Figure 1**.

RESULTS

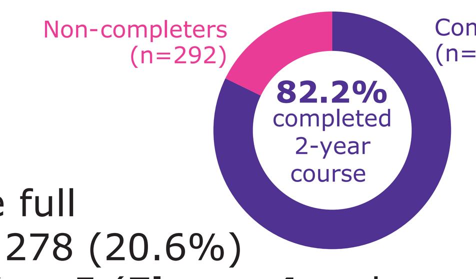
- A total of 1642 PwMS initiated cladribine tablets treatment and had follow-up into Year 5 or Year 6.
  - Overall, 67% of the study population were female, and 58% were 31–50 years of age.
- Among PwMS for whom prior treatment information was available (n=309), approximately 80% received cladribine tablets as either the first or second line of therapy (**Figure 2**).
  - Prior to cladribine tablets as the second line of therapy, dimethyl fumarate (n=27), fingolimod (n=24), and glatiramer acetate (n=21) were the most frequently used disease-modifying therapies (DMTs).

Figure 2. Cladribine Tablets Therapy Was Either the First or Second Line of Therapy for Most PwMS



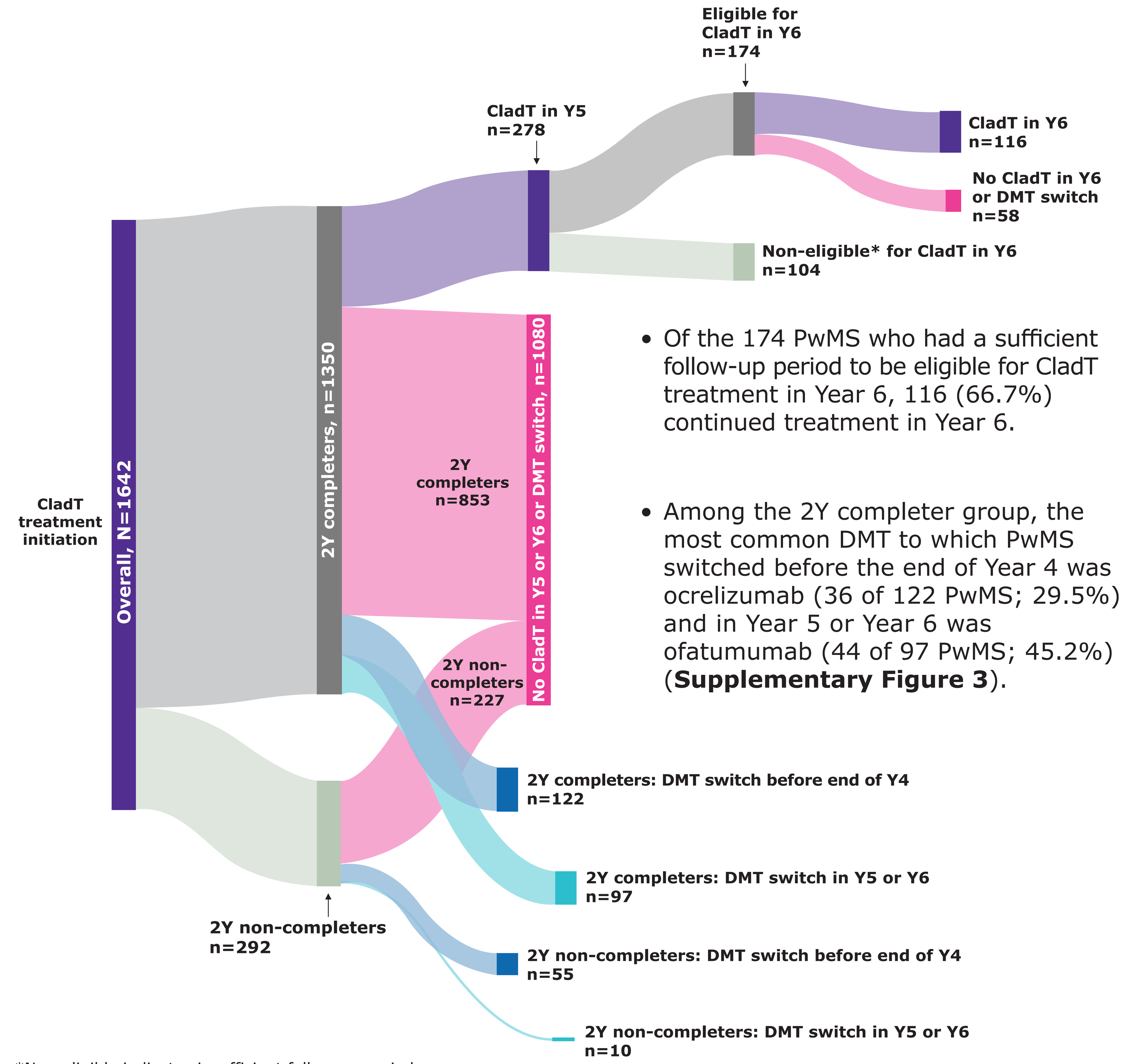
- During the observation period, 834 of 1642 PwMS (50.8%) did not receive a comedication. The most commonly used comedications were prednisolone (n=209, 12.7%) and methylprednisolone (n=207, 12.6%).
- Overall, 1350 of 1642 PwMS (82.2%) completed the full 2-year cladribine tablets treatment course (**Figure 3**).

Figure 3. Cladribine Tablets 2-Year Treatment Completion Rate Was High



- Among the 1350 PwMS who completed the full 2-year cladribine tablets treatment course, 278 (20.6%) continued cladribine tablets treatment in Year 5 (**Figure 4** and **Supplementary Figure 2**).
  - For the overall group, this was 278 of 1642 (16.9%).
- Among the 1350 PwMS who completed the full 2-year cladribine tablets treatment course, 853 (63.1%) were neither prescribed further cladribine tablets treatment in Year 5 or Year 6 nor switched DMT (**Figure 4** and **Supplementary Figure 2**).
  - For the overall group, this was 1080 of 1642 patients (65.8%).

Figure 4. Most PwMS Were Neither Prescribed Further Cladribine Tablets Treatment in Years 5 and 6 Nor Switched DMT



- Of the 174 PwMS who had a sufficient follow-up period to be eligible for CladT treatment in Year 6, 116 (66.7%) continued treatment in Year 6.
- Among the 2Y completer group, the most common DMT to which PwMS switched before the end of Year 4 was ocrelizumab (36 of 122 PwMS; 29.5%) and in Year 5 or Year 6 was ofatumumab (44 of 97 PwMS; 45.2%) (**Supplementary Figure 3**).

*Non-eligible indicates insufficient follow-up period.
Projected PwMS numbers are presented as approximate (rounded) whole numbers. See **Supplementary Methods** for details.
CladT, cladribine tablets; DMT, disease-modifying therapy; PwMS, people with multiple sclerosis; Y, year

CONCLUSIONS

- **Most PwMS (~82%) completed the full 2-year cladribine tablets treatment course.**
- **Cladribine tablets treatment was not received in Year 5 or Year 6, nor did any DMT switch occur, for 853 of 1350 (~63%) PwMS who completed 2 years of cladribine tablets treatment.**
- **Most PwMS who continued cladribine tablets treatment in Year 5 and had sufficient follow-up to be eligible for treatment in Year 6 did continue treatment in Year 6 (~67%).**

SCAN FOR AFFILIATIONS, DISCLOSURES, AND SUPPLEMENTARY MATERIALS

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Supplementary Materials

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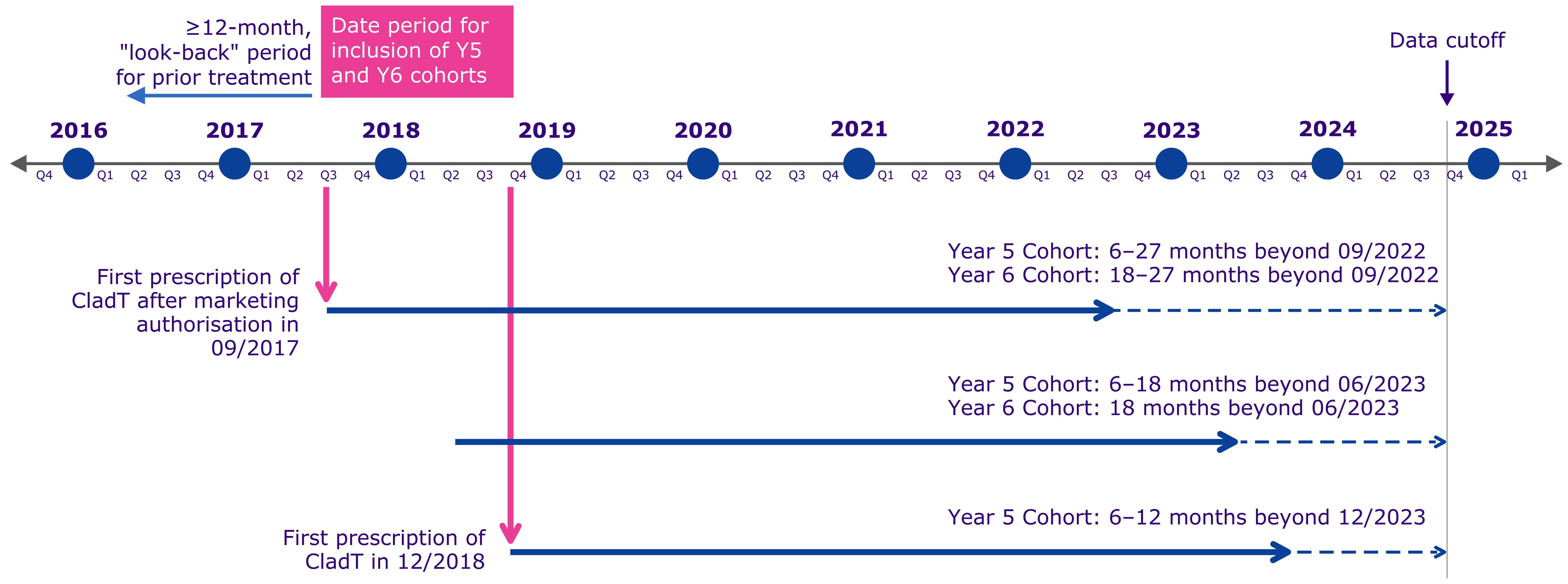
Supplementary Methods

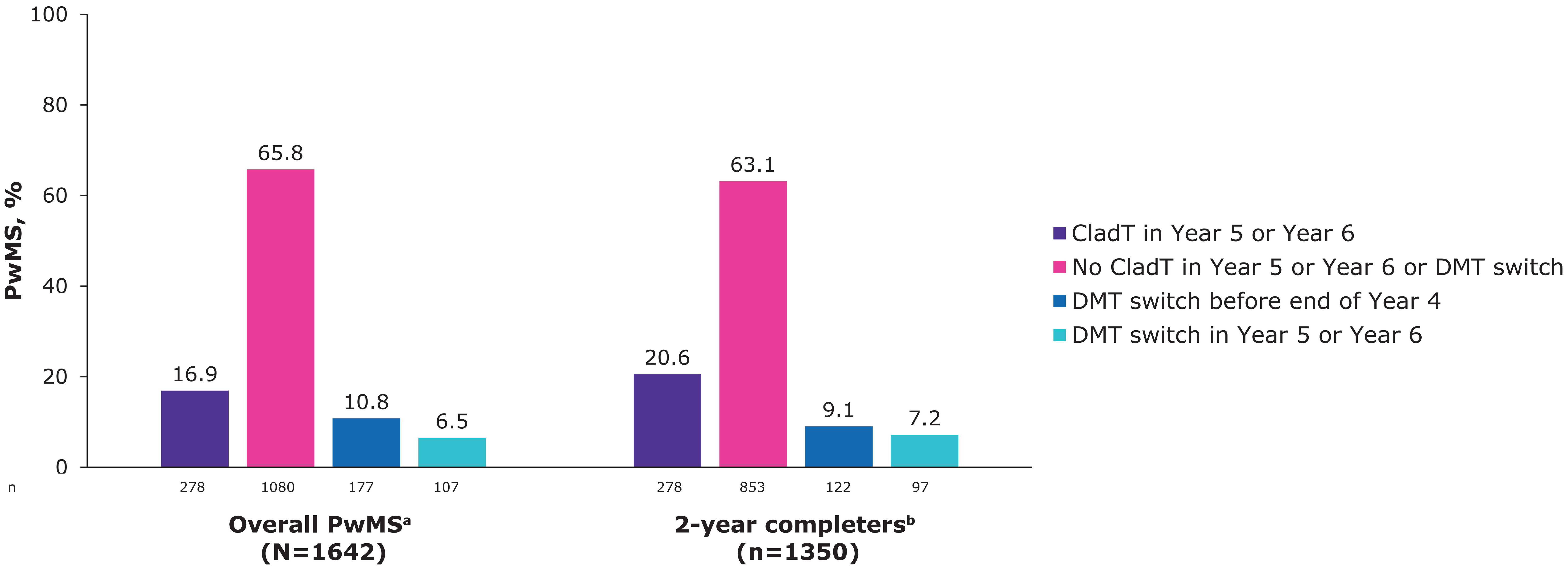
- Two IQVIA prescription database panels that cover different time frames were used.
  - The larger Trust Centre Panel (using projected data based on statutory health insurance and private health insurance) was used to determine the characteristics and treatment patterns of PwMS after the initiation of treatment with cladribine tablets.
    - Projection factors were determined by comparing the number of units between the IQVIA LRx (~80% coverage) and IQVIA Pharmascope (100% coverage) databases. IQVIA Pharmascope also incorporated a private health insurance panel in which the number of prescriptions in the private health insurance sector could be accurately determined, and this was used to calculate the projection factors on the statutory health insurance and private health insurance basis.
    - Due to the use of projection factors, data in the analyses using the Trust Centre Panel are not exact numbers. Percentages of PwMS were calculated using non-rounded numbers of PwMS. To streamline presentation, projected numbers are presented as approximate (rounded) whole numbers throughout the poster, with minor rounding adjustments applied to the Sankey diagrams where needed to reach whole number totals.
  - The smaller Long-Term Panel (using non-projected data) was composed of a specialised subset of patients from the Trust Centre Panel with enriched patient histories that included prescription data prior to 2015, which was the earliest date available in the Trust Centre Panel.
- Three cohorts of PwMS who initiated treatment with cladribine tablets were analysed, those who:
  - Continued cladribine tablets treatment in Year 5.
  - Were not prescribed cladribine tablets treatment in Year 5 or Year 6 and did not switch to another disease-modifying therapy (DMT) at any time after treatment initiation.
  - Switched to another DMT at any time after treatment initiation.
- PwMS who continued cladribine tablets treatment in Year 5 were also grouped by whether they received treatment with cladribine tablets in Year 6 or not.
- PwMS were defined as eligible for cladribine tablets treatment in Year 6 if there were ≥18 months from cladribine tablets treatment in Year 5 until the database cutoff date.

Supplementary Figure 1. Study Design



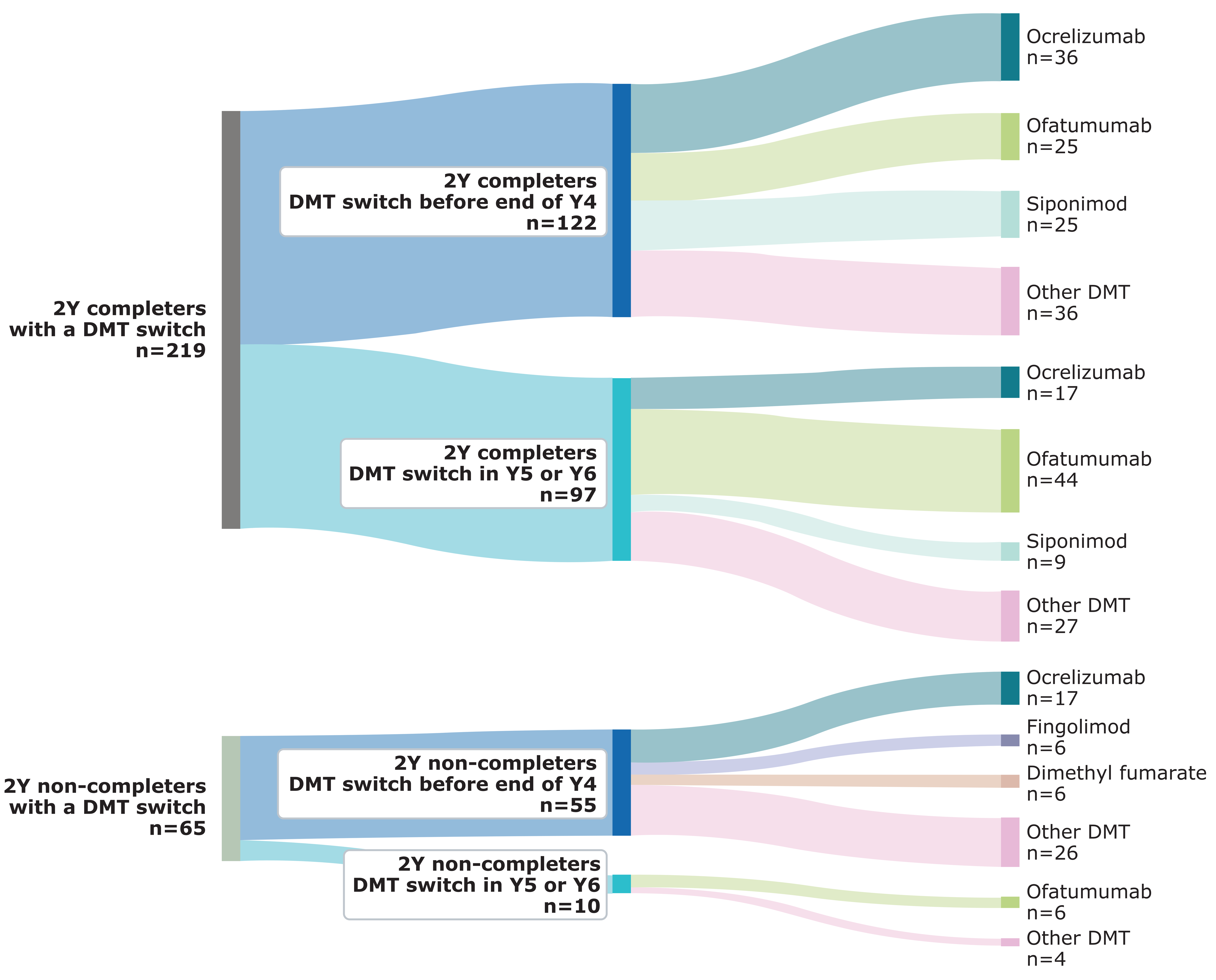
CladT, cladribine tablets; Q, quarter; Y, year

Supplementary Figure 2. Most PwMS, Both Overall and Those Who Completed the the Full 2-Year Cladribine Tablets Treatment Course, Were Neither Prescribed Further Treatment With Cladribine Tablets in Year 5 or Year 6 Nor Switched DMT



[a]PwMS who initiated CladT treatment and had follow-up into Year 5 or Year 6. [b]PwMS who completed the full 2-year CladT treatment regimen annual treatment courses in Years 1 and 2.
CladT, cladribine tablets; DMT, disease-modifying therapy; PwMS, people with multiple sclerosis

Supplementary Figure 3. Disease-Modifying Therapies to Which PwMS Switched. Overall, 177 PwMS switched DMT before the end of Year 4, of whom 53 (29.9%) switched to ocrelizumab; 107 PwMS switched DMT in Year 5 or Year 6, of whom 50 (46.7%) switched to ofatumumab



The overall PwMS group (N=1642) included both the 2Y completer (n=1350) and 2Y non-completer (n=292) groups. Not shown for the 2Y completer group are PwMS who received CladT in Year 5 (n=278) or who neither received CladT in Year 5 or Year 6 nor switched DMT (n=853). Not shown for the 2Y non-completer group are PwMS who neither received CladT in Year 5 or Year 6 nor switched DMT (n=227).
The three most common DMTs received within each group are shown, unless <5 patients received the DMT.
Projected PwMS numbers are presented as approximate (rounded) whole numbers. See **Supplementary Methods** for details.
DMT, disease-modifying therapy; Y, year