

# Stability of Employment Status Among Patients With Highly Active Relapsing Multiple Sclerosis During the 2-year CLARIFY-MS Study

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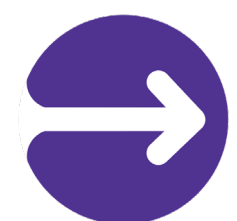


## CONCLUSIONS

Most patients with highly active RMS who received CladT and were employed at Baseline retained their employment after 2 years



As these data were gathered during the global COVID-19 pandemic, which substantially impacted employment, the stability reported here is reassuring



## INTRODUCTION

- In multiple sclerosis (MS), worsening of disability over time may lower a patient's ability to work, leading to absenteeism, low productivity, job changes, part time work or unemployment. In addition to its societal economic costs, inability to work may substantially impact patients' overall quality of life (QoL)<sup>1</sup>
- The CLARIFY-MS (NCT03369665) study, designed to evaluate the health-related QoL of patients with highly active relapsing MS (RMS) treated with cladribine tablets (CladT), also assessed the employment status of the patients during the study



## OBJECTIVE

To report the outcomes of exploratory analyses regarding the employment status of patients treated with CladT over 2 years in the CLARIFY-MS study



## METHODS

- CLARIFY-MS was a 2-year, prospective, open-label, single-arm, multicenter, phase IV study (**Supplementary Figure 1**)
- Patients with highly active RMS were recruited per the Summary of Product Characteristics of CladT, and eligible patients received CladT 3.5 mg/kg cumulative dose over 2 years
  - Highly active RMS was defined as one relapse in the previous year and  $\geq 1$  T1 gadolinium-enhancing lesion or  $\geq 9$  T2 lesions, while receiving treatment with other disease-modifying therapies (DMTs); or  $\geq 2$  relapses in the previous year, whether on DMT treatment or not
- Current employment status of patients who received  $\geq 1$  dose of CladT (full analysis set [FAS]), was determined using a survey at Baseline and Month 24
- Subgroup analyses were performed for patients who did not receive any DMTs before CladT (pre-treatment naïve subgroup), and those who received DMTs at any time prior to the start of treatment with CladT (prior DMT subgroup)
- Shifts in employment status of the patients during the study period were also analyzed
- Data were analyzed descriptively



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**REFERENCES:** 1. Jones E, et al. *BMC Health Serv Res.* 2016;16:294.

**DISCLOSURES:** **KS** has received honoraria for speaking, consulting and serving for advisory boards for Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and TG Therapeutics. **DL** has participated in speaker bureau for Almirall, Bayer, Biogen, the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, Sanofi, and Teva; and has received consultancy fees from Bayer, Biogen, the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and Teva; and has received research grants from Bayer, Biogen, the healthcare business of Merck KGaA, Darmstadt, Germany, and Novartis. **BB** has received consultancy fees, speaker fees, research grants (non-personal), or honoraria from Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and Sanofi. **EKH** has received honoraria/research support from Actelion (Janssen/J&J), Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, Sanofi, and Teva; and has served on advisory boards for Actelion (Janssen/J&J), Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and Sanofi. **JL-S** has accepted travel compensation from Biogen, the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, and Sanofi. Her institution received the honoraria for talks and advisory board commitments as well as research grants from Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, Sanofi, and Teva. **XM** has received speaking honoraria and travel expenses for participation in scientific meetings, has been a steering committee member of clinical trials or participated in advisory boards of clinical trials in the past years with AbbVie, Actelion, Alexion, Biogen, Celgene (BMS), EMD Serono, Genzyme, Hoffmann-La Roche, Immunic, Janssen Pharmaceuticals, MedDay, the healthcare business of Merck KGaA, Darmstadt, Germany, Mylan, Nervgen, Novartis, Sandoz, Sanofi-Genzyme, Teva Pharmaceutical, TG Therapeutics, Excemed, MSIF and NMSS. **FPa** has served on scientific Advisory Boards for Almirall, Bayer, Biogen, Celgene (BMS), the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, Roche, Sanofi, and Teva; he also received speaker honoraria from the same companies and non-personal research grants for his department from Biogen, the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, and Sanofi. **FPI** has received research grants from the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, and Sanofi, and fees for serving as a member of the DMC in clinical trials with Parexel, Lundbeck and Roche. **AS** has served on advisory boards for the healthcare business of Merck KGaA, Darmstadt, Germany, Novartis, and Sanofi, and has been invited to speak on behalf of Almirall, Biogen, Excemed, the healthcare business of Merck KGaA, Darmstadt, Germany, and Teva. **NA, AN, AL** and **ASm**, are employees of the healthcare business of Merck KGaA, Darmstadt, Germany.

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## RESULTS

- All 482 patients in the FAS completed the employment survey at Baseline (pre-treatment naïve, N=134; prior DMT, N=348); employment data were missing for 46 patients at Month 24

### Overall Employment Status

- There were no major differences in the employment status of the patients at Baseline and Month 24 in the FAS. Over 40% of the patients had full-time employment during the study (**Figure 1**)
- Results of the pre-treatment naïve and prior DMT subgroups were mostly consistent with those of the FAS (**Figure 1**)

### Shifts in Employment Status

- Shifts in employment status from Baseline to Month 24 in the FAS are presented in **Table 1** and **Figure 2**. Shifts in employment status among the subgroups were mostly consistent with that in the FAS (**Figure 2; Supplementary Tables 1A,B**)

Table 1: Shifts in employment status of patients from Baseline to Month 24/ES in the FAS

Baseline	Month 24/ES Employment Status						
Employment Status, n (%)	Unemployment n (%)	Sick leave n (%)	Employed Part-time n (%)	Employed Full-time n (%)	Education n (%)	Homemaker n (%)	Missing n (%)
Unemployment, 78 (16.2)	49 (10.2)	3 (0.6)	10 (2.1)	4 (0.8)	0 (0.0)	3 (0.6)	9 (1.9)
Sick Leave, 37 (7.7)	6 (1.2)	14 (2.9)	2 (0.4)	10 (2.1)	0 (0.0)	2 (0.4)	3 (0.6)
Employed Part-time, 56 (11.6)	4 (0.8)	2 (0.4)	23 (4.8)	13 (2.7)	0 (0.0)	4 (0.8)	10 (2.1)
Employed Full-time, 229 (47.5)	16 (3.3)	8 (1.7)	20 (4.1)	165 (34.2)	0 (0.0)	2 (0.4)	18 (3.7)
Education, 37 (7.7)	3 (0.6)	1 (0.2)	2 (0.4)	11 (2.3)	16 (3.3)	0 (0.0)	4 (0.8)
Homemaker, 45 (9.3)	14 (2.9)	0 (0.0)	2 (0.4)	6 (1.2)	0 (0.0)	21 (4.4)	2 (0.4)
Missing, 0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total, 482 (100.0)	92 (19.1)	28 (5.8)	59 (12.2)	209 (43.4)	16 (3.3)	32 (6.6)	46 (9.5)

ES, end of study; FAS, full analysis set

Figure 2: Shifts in employment status of patients from Baseline to Month 24/ES – (A) FAS, (B) Pre-treatment naïve subgroup, (C) Prior DMT subgroup

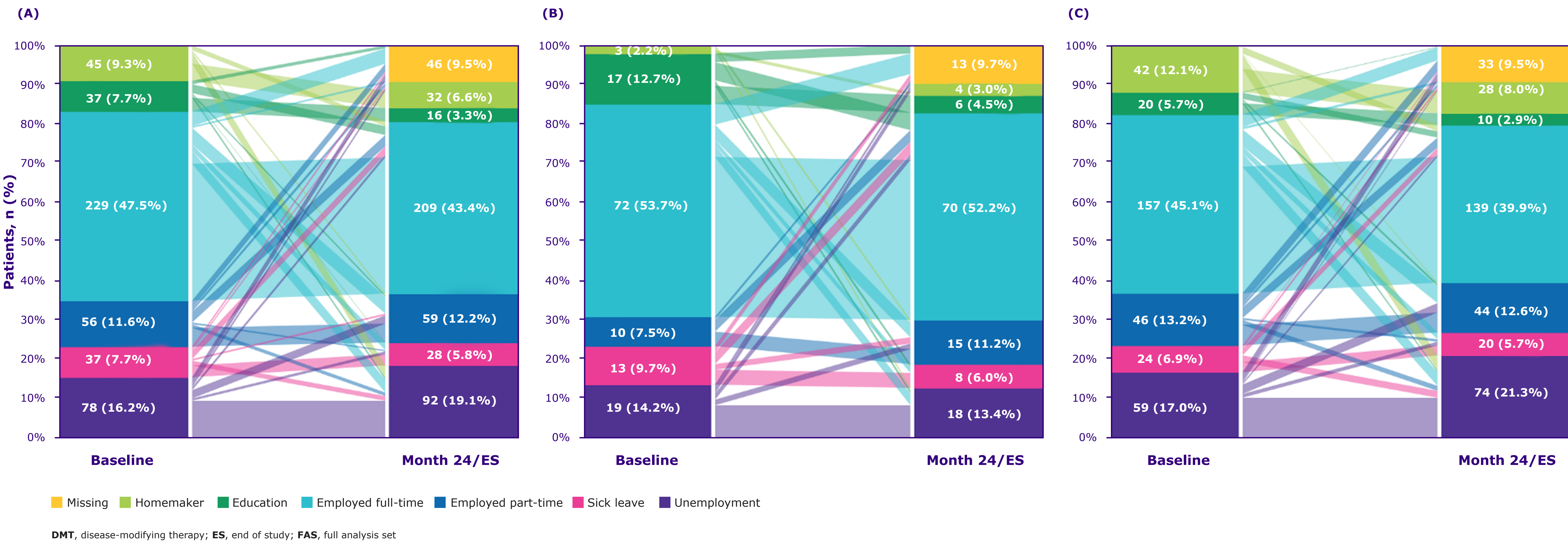
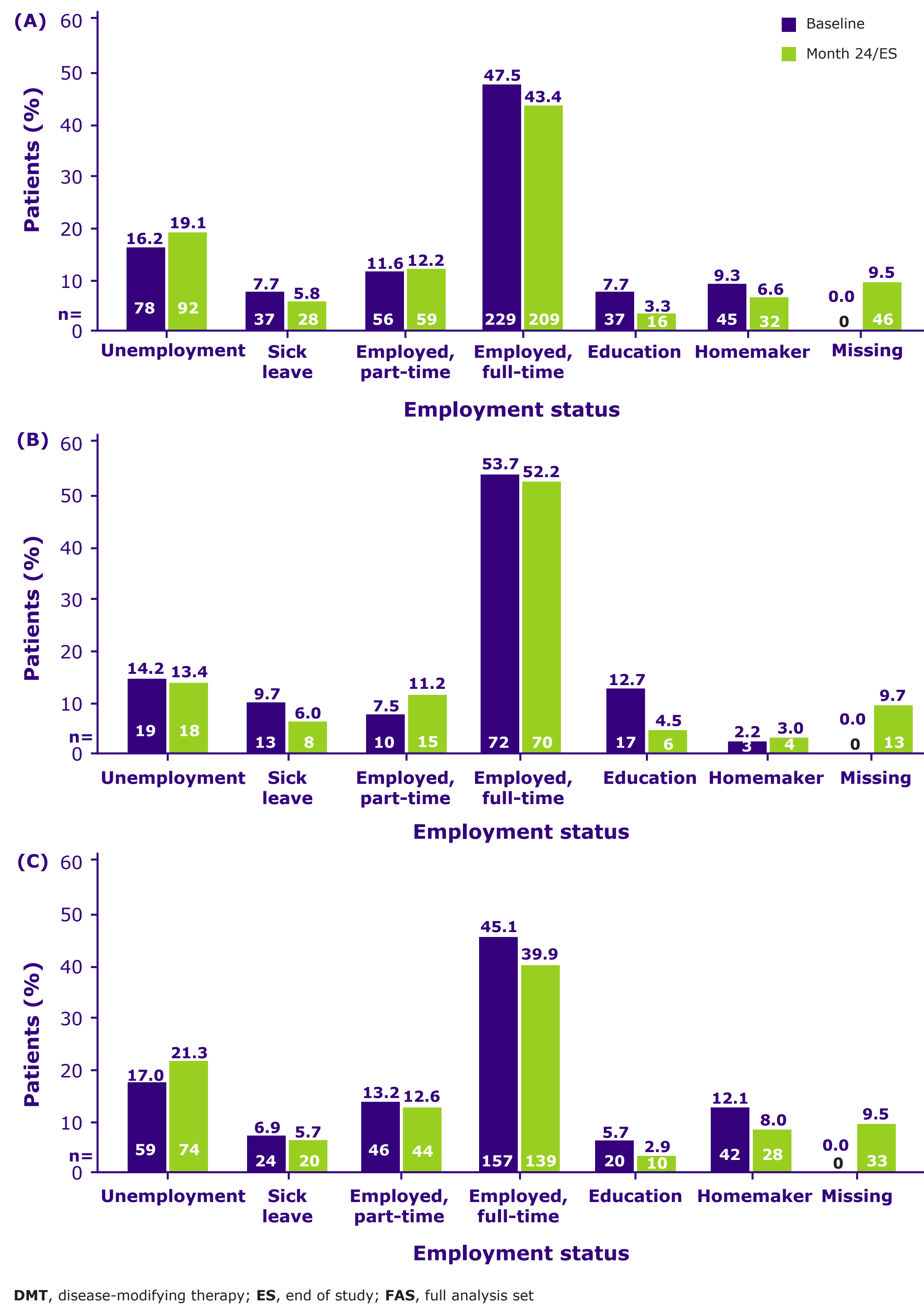
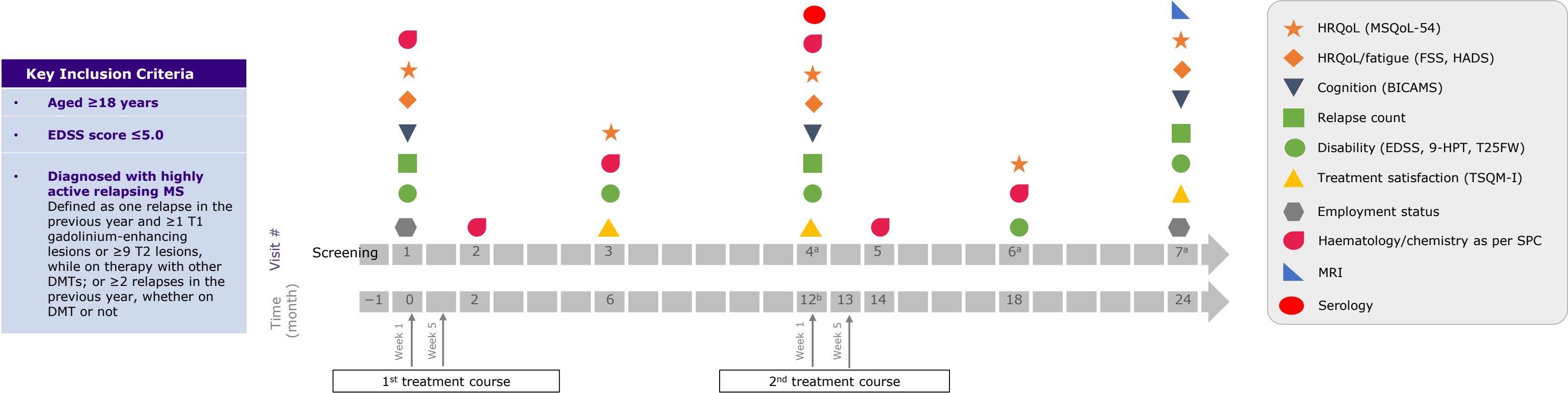


Figure 1: Employment status of patients at Baseline and Month 24/ES – (A) FAS, (B) Pre-treatment naïve subgroup, (C) Prior DMT subgroup





Supplementary Figure 1: CLARIFY-MS key inclusion criteria and study design



<sup>a</sup>0–3 month window for these trial visits. <sup>b</sup>Second treatment course may be delayed for some patients.  
#, number; 9-HPT, Nine-Hole Peg Test; BICAMS, Brief International Cognitive Assessment for Multiple Sclerosis; DMT, disease-modifying therapy; EDSS, Expanded Disability Status Scale; FSS, Fatigue Severity Scale; HADS, Hospital Anxiety and Depression Scale; HRQoL, health-related quality of life; MRI, magnetic resonance imaging; MSQoL-54, Multiple Sclerosis Quality of Life-54 instrument; RMS, relapsing multiple sclerosis; SPC, summary of product characteristics; T25FW, Timed 25-Foot Walk; TSQM, Treatment Satisfaction Questionnaire for Medication.

Supplementary Table 1A: Shifts in employment status of patients from Baseline to Month 24/ES in the Pre-treatment naïve subgroup

Baseline	Month 24/ES Employment Status						
Employment Status, n (%)	Unemployment n (%)	Sick leave n (%)	Employed Part-time n (%)	Employed Full-time n (%)	Education n (%)	Homemaker n (%)	Missing n (%)
Unemployment, 19 (14.2)	12 (9.0)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)	2 (1.5)	1 (0.7)
Sick Leave, 13 (9.7)	0 (0.0)	5 (3.7)	2 (1.5)	4 (3.0)	0 (0.0)	0 (0.0)	2 (1.5)
Employed part-time, 10 (7.5)	0 (0.0)	0 (0.0)	5 (3.7)	4 (3.0)	0 (0.0)	1 (0.7)	0 (0.0)
Employed Full-time, 72 (53.7)	4 (3.0)	2 (1.5)	5 (3.7)	54 (40.3)	0 (0.0)	0 (0.0)	7 (5.2)
Education, 17 (12.7)	1 (0.7)	1 (0.7)	0 (0.0)	6 (4.5)	6 (4.5)	0 (0.0)	3 (2.2)
Homemaker, 3 (2.2)	1 (0.7)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Missing, 0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total, 134 (100.0)	18 (13.4)	8 (6.0)	15 (11.2)	70 (52.2)	6 (4.5)	4 (3.0)	13 (9.7)

ES, end of study

Supplementary Table 1B: Shifts in employment status of patients from Baseline to Month 24/ES in the Prior DMT subgroup

Baseline	Month 24/ES Employment Status						
Employment Status, n (%)	Unemployment n (%)	Sick leave n (%)	Employed Part-time n (%)	Employed Full-time n (%)	Education n (%)	Homemaker n (%)	Missing n (%)
Unemployment, 59 (17.0)	37 (10.6)	3 (0.9)	8 (2.3)	2 (0.6)	0 (0.0)	1 (0.3)	8 (2.3)
Sick Leave, 24 (6.9)	6 (1.7)	9 (2.6)	0 (0.0)	6 (1.7)	0 (0.0)	2 (0.6)	1 (0.3)
Employed part-time, 46 (13.2)	4 (1.1)	2 (0.6)	18 (5.2)	9 (2.6)	0 (0.0)	3 (0.9)	10 (2.9)
Employed Full-time, 157 (45.1)	12 (3.4)	6 (1.7)	15 (4.3)	111 (31.9)	0 (0.0)	2 (0.6)	11 (3.2)
Education, 20 (5.7)	2 (0.6)	0 (0.0)	2 (0.6)	5 (1.4)	10 (2.9)	0 (0.0)	1 (0.3)
Homemaker, 42 (12.1)	13 (3.7)	0 (0.0)	1 (0.3)	6 (1.7)	0 (0.0)	20 (5.7)	2 (0.6)
Missing, 0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total, 348 (100.0)	74 (21.3)	20 (5.7)	44 (12.6)	139 (39.9)	10 (2.9)	28 (8.0)	33 (9.5)

DMT, disease-modifying therapy; ES, end of study