

## INTRODUCTION

Real-world treatment cohorts serve as an important measure in the long-term evaluation of safety and efficacy of MS immunotherapy. In 2001, the German MS society has initiated a general MS registry for Germany (GMSR) collecting routine clinical data including treatment whenever documented by the treating neurologist. In 2010, the prospective observational cohort study NationMS has started patient recruitment for a defined set of therapy-naive patients with early MS or clinically isolated syndrome (CIS) in the assigned study centers with regular yearly and bi-yearly visits following a defined assessment plan.

## PURPOSE

To compare patients' demographic and disease characteristics from two different major data sources and to assess early disability evolution.

## METHODS

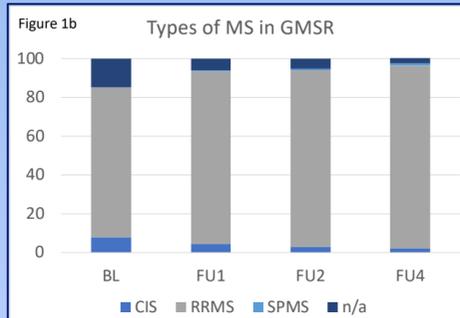
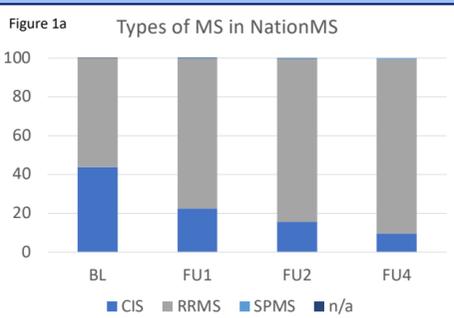
- NationMS, all monitored and approved datasets until 31-Dec-2019 were included
- GMSR, a subcohort was identified by applying inclusion criteria similar to NationMS
- Baseline characteristics were analyzed for every cohort separately
- Statistical comparisons with Chi-square tests ( $\chi^2$ -test) and t-tests
- All values were given as mean  $\pm$  standard deviation (SD) and 95% confidence interval (CI), p-values < 0.01 were indicated with \*\*

## RESULTS – Demography

The final cohorts analyzed comprised n=1374 [NationMS] and n=2130 [GMSR] datasets, respectively.

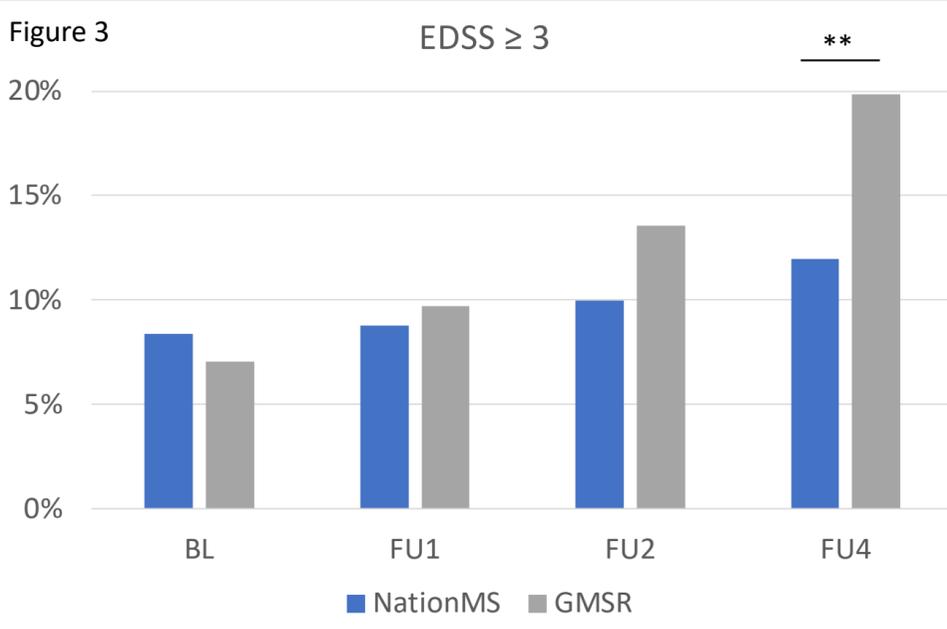
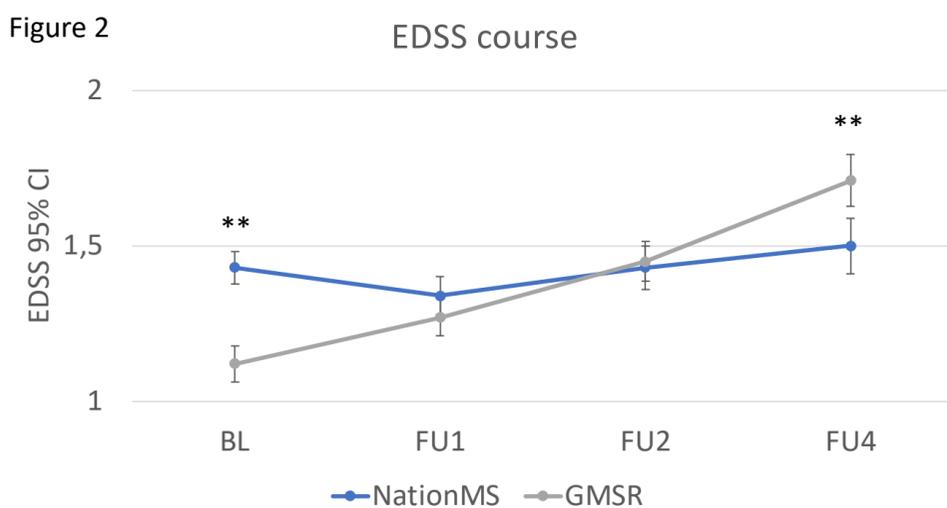
Both cohorts were comparable in regard to sex-ratio (70% females [NationMS] & 71% [GMSR]), age at onset (32.8 $\pm$ 9.7 & 34.1 $\pm$ 10.7), age at diagnosis (33.1 $\pm$ 9.7 & 34.4 $\pm$ 10.8), time to diagnosis (3.8  $\pm$ 6.5 & 3.1  $\pm$ 4.7 months) (table1).

Table 1	NationMS	GMSR
<b>N</b>	1374	2130
<b>Age at disease onset [years]</b> Mean $\pm$ SD	32.82 $\pm$ 9.7	34.1 $\pm$ 10.7
<b>Age at first diagnosis</b> Mean $\pm$ SD	33.14 $\pm$ 9.7	34.4 $\pm$ 10.8
<b>Age at baseline / register entry</b> Mean $\pm$ SD	33.78 $\pm$ 9.7	36.4 $\pm$ 10.9
<b>Diagnosis time [month]</b> Mean $\pm$ SD	3.81 $\pm$ 6.5	3.1 $\pm$ 4.7
<b>Disease duration cohort [month]</b> Mean $\pm$ SD	79.52 $\pm$ 21.7	68.1 $\pm$ 36.2
<b>Sex n (%)</b>		
<b>female</b>	963 (70.1)	1516 (71.2)
<b>male</b>	411 (29.9)	614 (28.8)



## RESULTS II – Follow-up

After 4 years of follow-up (N=720 & 1114), 0.7% [NationMS] & 1.2% [GMSR] had converted to clinical assigned SPMS (figures 1a+b,  $\chi^2$ -test p=0.41) and 11.8% [NationMS] & 19.8% [GMSR] developed an EDSS $\geq$ 3 (figure 3,  $\chi^2$ -test, p=0.001). The EDSS course differs significant between the two cohorts at baseline and after 4 years of follow-up (figure 2, t-test p=0.001).



## CONCLUSION

Our results show that patients which were treatment-naive at recruitment (NationMS) had comparable baseline characteristics to those in the GMSR, adjusted for inclusion criteria similar to NationMS. Data at follow-up after four years indicate a significantly higher proportion of patients reaching a disability level of EDSS  $\geq$ 3, but a similarly low rate of conversion to SPMS. Further analyses are due to identify factors influencing EDSS-outcomes at year 4 and beyond.

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