ReMuS MULTIPLE SCLEROSIS PATIENT REGISTRY

Regular Output from ReMuS Registry

Data export updated on 30. 6. 2017

– Summary Report

In Prague, 14th September 2017

Endowment fund IMPULS
Kateřinská 30, Praha 2, ID: 26169428
www.multiplesclerosis.cz

Contents

1 Introduction

Czech National Registry of Multiple Sclerosis (ReMuS) was mainly created to obtain data on the prevalence, incidence, severity at the time of diagnosis and clinical course of multiple sclerosis (MS), its clinical symptoms, relapses, progression, MS treatment, disability development, comorbidities and causes of death. The objective is to provide outputs for cost and effectiveness monitoring of health care and medicinal preparations, assessment of information to be provided to health care payers, other public institutions and manufacturers of medicinal products to assess the seriousness of MS and its socioeconomic impacts from the scientific, epidemiologic and statistical perspective.

Based on acquired data, it will be possible to look for possible risk factors both for the development of MS itself and lack of effectiveness of treatment or more rapid progression of the disease. Information on course of MS will enable health care payers to better plan the allocation of financial means necessary for the treatment of this disease. Information on treatment effectiveness is instrumental in the selection of the therapy and implementation of changes or modifications when relevant.

The registry now includes only multiple sclerosis patients who:

- undergo treatment in one of the participating MS treatment centres
- have signed informed consent with processing their personal and clinical data in ReMuS registry.

The detailed analysis contains only patients who attended their appointment within the first half of 2017 (or within the last year in case of non-DMD patients). The analysis is presented in two sections. The main part treats DMD/IVIG patients and is identical for all centres. The second part summarizes preliminary results for non-DMD patients and is present only for MS centres which enter the non-DMD patients into the registry.

Endowment fund IMPULS
Kateřinská 30, Praha 2, ID: 26169428
www.multiplesclerosis.cz

2 Results – DMD/IVIG patients

As of 30. 6. 2017, ReMuS registry included data of patients from fifteen MS treatment centres – General University Hospital in Prague (VFN), Hospital in Teplice, Hospital in Jihlava, University Hospital Motol in Prague, University Hospital in Plzeň, Hospital of Pardubice Region, University Hospital in Ostrava, University Hospital Královské Vinohrady in Prague, Thomayer University Hospital in Prague in Krč, University Hospital in Hradec Králové, University Hospital in Brno in Bohunice, University Hospital in Olomouc, Hospital in České Budějovice, University Hospital St. Anna in Brno and Regional Hospital T. Baťa in Zlín. For the main analysis, we included data of patients who were treated in the period from 1. 1. 2013 with one of the DMD and IVIG preparations listed below and for whom current data were available:

- DMDs – Aubagio, Avonex, Betaferon, Copaxone[20], Copaxone[40], Extavia, Gilenya, Lemtrada, Plegridy, Rebif[22], Rebif[44], Tecfidera, Tysabri
- IVIGs – Endobulin, Flebogamma, Gammagard, Kiovig, Octagam.

Patients classified as “non-DMD“ are also included into the present analysis for centres with such data available. These patients had been treated with DMD or IVIG only before 1. 1. 2013 or haven´t used these products at all.

Table 1 gives the final number of DMD/IVIG patients included in ReMuS registry as of 30. 6. 2017. The first column contains the total number of DMD/IVIG patients in the registry (patients fulfilling the condition of informed consent and DMD or IVIG treatment), while the number of patients with current data (last visit in the first half of 2017) who were included in the current analysis is given in the second column.

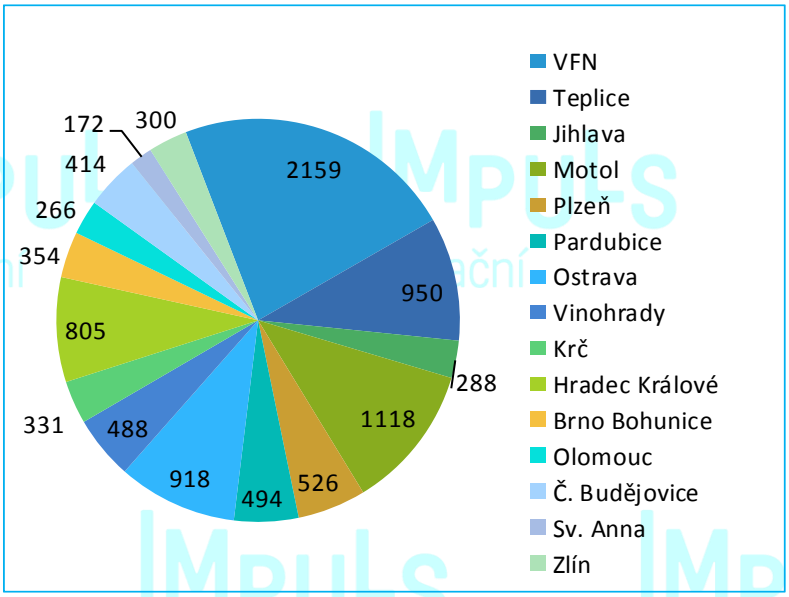

Figure 1 Total number of analysed DMD/IVIG patients by centres

Table 1 Total number of DMD/IVIG patients by centres

Centre	Patients in the registry	Analysed patients	Percentage in the analysis
VFN	2225	2159	22,5%
Teplice	983	950	9,9%
Jihlava	295	288	3,0%
Motol	1169	1118	11,7%
Plzeň	568	526	5,5%
Pardubice	512	494	5,2%
Ostrava	936	918	9,6%
Vinohrady	500	488	5,1%
Krč	341	331	3,5%
Hradec Králové	838	805	8,4%
Brno Bohunice	364	354	3,7%
Olomouc	276	266	2,8%
České Budějovice	429	414	4,3%
Sv. Anna	173	172	1,8%
Zlín	302	300	3,1%
Total	9911	9583	100%

The table and figure below illustrate the development of the number of DMD/IVIG patients and centres participating in ReMuS registry since its creation. The first data export in summer 2013 analysed data originating from three centres - a total of 1501 patients. Now, in June 2017, the registry has expanded to include all 15 MS treatment centres. The data of 9583 patients from all over the Czech Republic enter the analysis.

Table 2 Number of DMD/IVIG patients in the ReMuS registry – development in time

Data export date	Number of centres	Number of patients to be analysed	Data export date	Number of centres	Number of patients to be analysed
30.06.2013	3	1501	30.06.2016	14	8353
31.12.2013	7	2920	31.12.2016	15	9044
30.06.2014	12	4715	30.06.2017	15	9583
31.12.2014	12	5639			
30.06.2015	13	7099			
31.12.2015	13	7786			

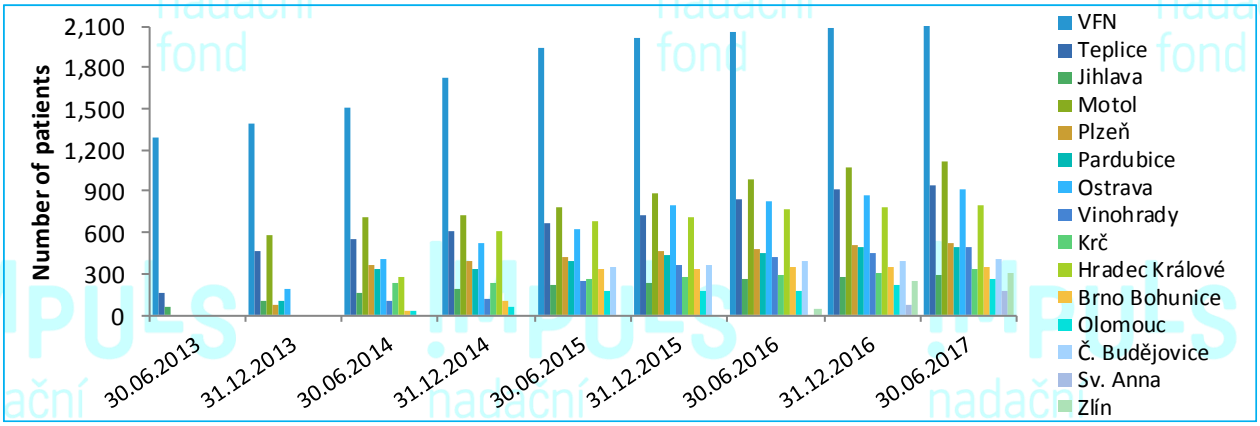

Figure 2 Number of DMD/IVIG patients in the registry contributed by individual centres – development in time

2.1 Demographic data

2.1.1 Sex

Taken together, all centres treat 71.5% women and 28.5% men.

Table 3 Patient distribution by sex

Sex	All centres	
	Number	Percentage
Females	6853	71.5%
Males	2730	28.5%

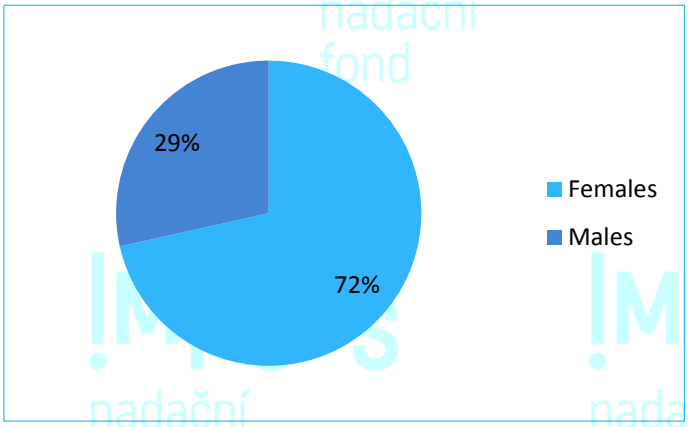

Figure 3 Patient distribution by sex

2.1.2 Age at last patient visit

Mean age at last visit is 41.6 years. Overall, the registry now includes 32 patients younger than 18 years, and 8 of these are younger than 15 years. When all MS treatment centres are taken together the most represented age group is that of patients aged 40–50 years.

Table 4 Patient age in years at last visit

Centre	Mean	Median	Minimum	Maximum	SD	Number of missing values
All centres	41.6	41.1	7.7	79.7	10.4	0

Table 5 Patient age in years at last visit by sex

Centre	Sex	Mean	Median	Minimum	Maximum	SD	Number of missing values
All centres	Females	41.9	41.5	11.2	75.8	10.5	0
	Males	40.8	40.1	7.7	79.7	10.1	0

Table 6 Number of patients younger than 15 and 18 let, respectively

Age	All centres	
	Number	Percentage
< 15 years	8	0.1%
< 18 years	32	0.3%

Table 7 Number of patients in individual groups by decades

Age	All centres	
	Number	Percentage
0 – 10	1	0.0%
10 – 20	76	0.8%
20 – 30	1277	13.3%
30 – 40	2985	31.1%
40 – 50	3176	33.1%
50 – 60	1578	16.5%
60 – 70	463	4.8%
70 – 80	27	0.3%
80 – 90	0	0.0%
90 – 100	0	0.0%

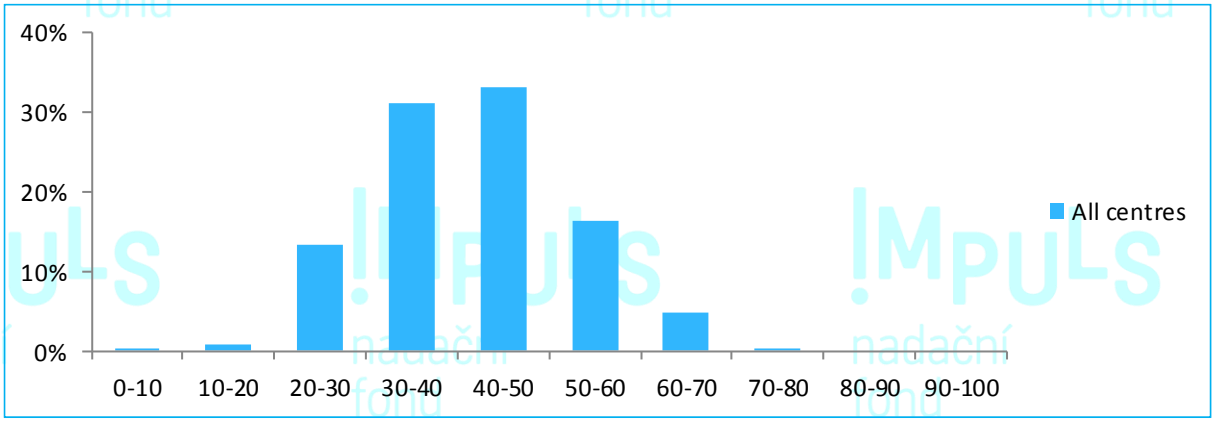

Figure 4 Patient distribution by age

2.1.3 Age at disease onset

Date of disease onset is an important parameter that is used to calculate patient age at disease onset and disease duration period.

Mean age at disease onset is 30.9 years. Table 8 shows, however, that patient age at disease onset ranged from 3 years to 67 years.

Table 8 Patient age in years at the time of disease onset

Centre	Mean	Median	Minimum	Maximum	SD	Number of missing values
All centres	30.9	29.7	3.3	67.3	9.6	4

2.1.4 Patient distribution by individual healthcare insurance companies

Table 9 and Figure 5 show the distribution of patients in the registry by individual health insurance companies. 57.8% of patients are insured with the General Health Insurance Company (code: 111) and 13.2% are insured with Health Insurance Company of the Ministry of Internal Affairs (code: 211).

Table 9 Patient distribution by health insurance companies

Health Insurance Co.	All centres	
	Number	Percentage
111	5537	57.8%
201	542	5.7%
205	905	9.4%
207	919	9.6%
209	142	1.5%
211	1268	13.2%
213	266	2.8%
Other*	4	0.0%

* "Other" stays mostly for self-payers

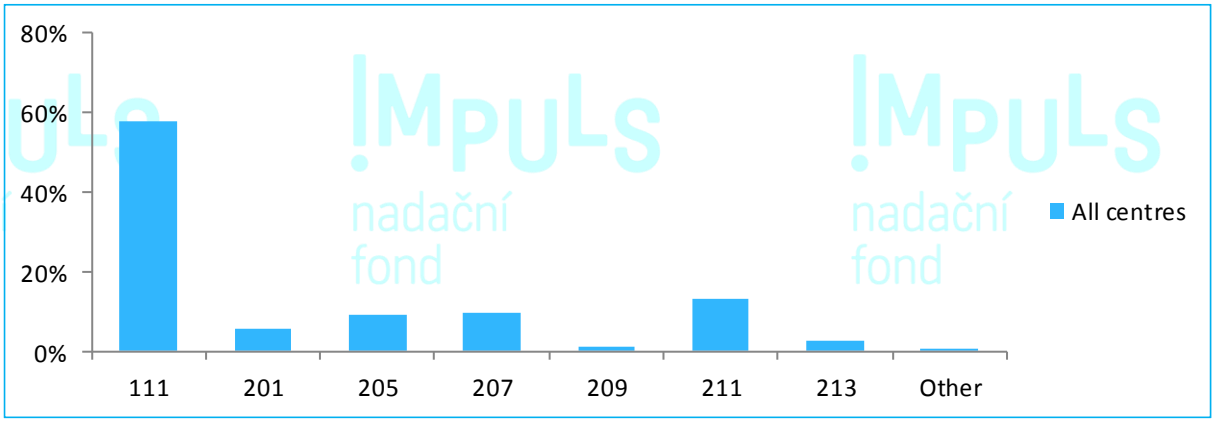

Figure 5 Patient distribution by health insurance companies

2.1.5 Patient distribution by regions

The registry makes it possible to obtain data on patient distribution by individual Czech Republic regions based on ZIP codes attached to patient residence addresses. ZIP codes assigned to communities that were part of two regions were assigned to the region that included most of the included communities. ZIP codes not found in the ZIP code registry of the Czech National Postal Office (Czech Post) were interpreted as incorrect.

The registry includes patients from all Czech Republic regions.

Table 10 Patient distribution by regions of their residence

Regions	All centres	
	Number	Percentage*
South Bohemia	588	6.1%
South Moravia	468	4.9%
Karlovy Vary	238	2.5%
Vysočina	519	5.4%
Hradec Králové	622	6.5%
Liberec	424	4.4%
Moravia-Silesia	881	9.2%
Olomouc	256	2.7%
Pardubice	594	6.2%
Plzeň	451	4.7%
Prague	1812	18.9%
Central Bohemia	1521	15.9%
Ústí nad Labem	758	7.9%
Zlín	446	4.7%

* 4 patients have permanent residence in Slovakia and 1 patient in Poland

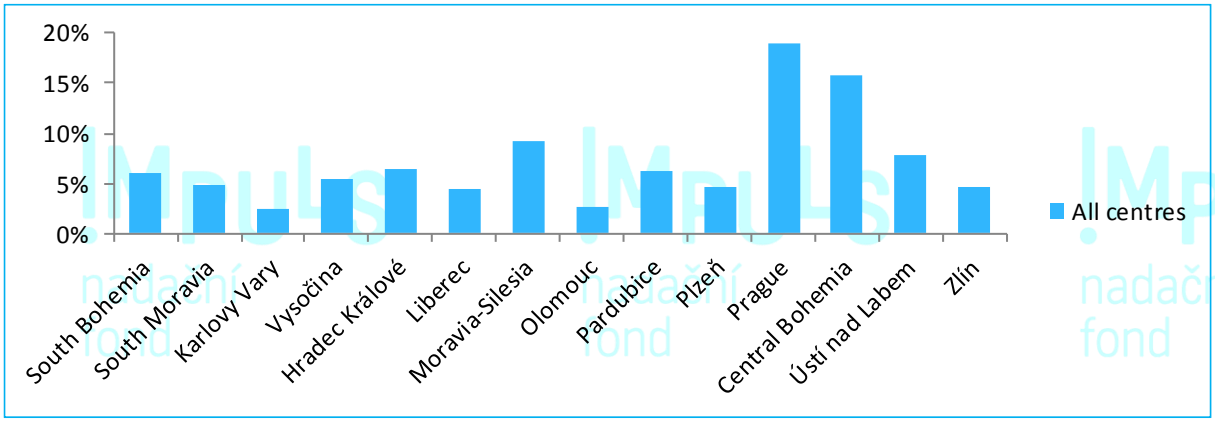

Figure 6 Patient distribution by regions of their residence

2.2 Employment and social benefits

Employment and provision of social benefits are evaluated based on data obtained at last visit. These parameters must be completed at each visit even when the condition remains the same.

It should be noted that all possibilities and combinations of employment and especially those for social benefits cannot be appreciated and the clarity and purposefulness of the output is preserved at the same time. It was thus necessary to introduce certain preference criteria so the physicians would be able to complete the data and decide what options to choose in unclear combined cases. These preference criteria (that is that the type of disability pension [DP] takes precedence over unemployment benefits or maternal leave [ML]) must be taken into account when interpreting and presenting this type of data.

2.2.1 Employment

As part of entering employment data, selection must be made among the options PTE – part-time employment, FTE – full-time employment, DNW – does not work (irrespective of the reasons for employment/unemployment and possible social benefits) and STUDENT – studies (social and health insurance is paid for by the state).

More than one half of the patients have full-time employment (57.8%), followed by 13.9% patients who work part-time.

Table 11 Patient distribution by employment

Employment	All centres	
	Number	Percentage*
PTE	1336	13.9%
FTE	5538	57.8%
DNW	2167	22.6%
STUDENT	246	2.6%

* 3.1% patients did not have data on employment completed

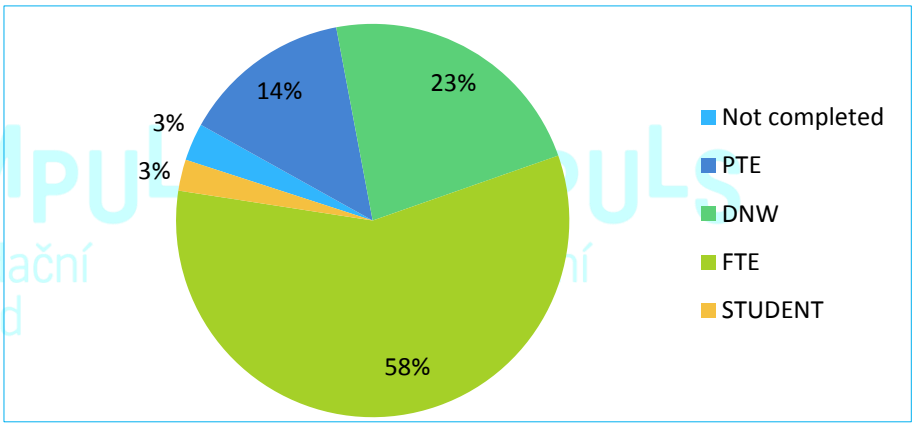

Figure 7 Patient distribution by employment

2.2.2 Social benefits

The structure of social benefits is based on simplified data as the completer had always to choose one, "most important" benefit in cases where a patient was receiving more benefits. DP1, DP2 and DP3 are social benefits that were of most interest to us - these codes denote 3 degrees of disability pension. ML – maternity leave is only reported as secondary information, as are unemployment benefits (UNEMPL). OAP codes for old-age pension.

55.6% of patients do not receive any social benefit.

Table 12 Patient distribution by type of social benefit

Social benefit	All centres	
	Number	Percentage*
DP1	1305	13.6%
DP2	717	7.5%
DP3	1072	11.2%
ML	563	5.9%
UNEMPL	73	0.8%
OAP	229	2.4%
Does not receive (X)	5325	55.6%

* 3.1% patients had no data completed for social benefits

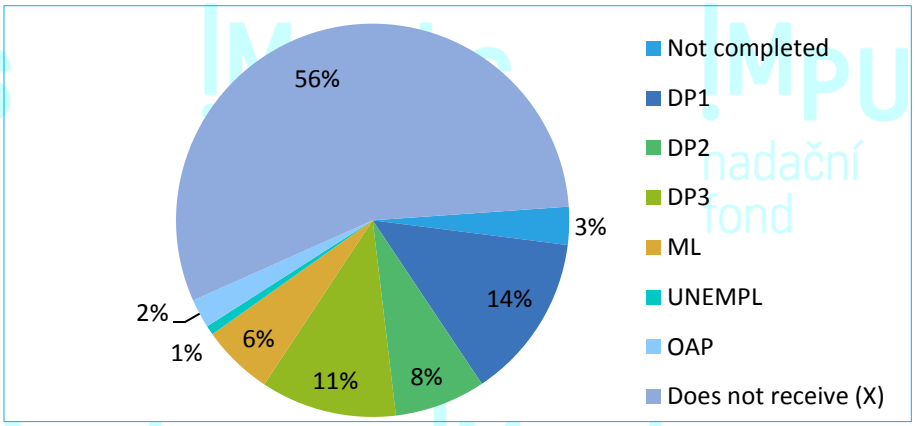

Figure 8 Patient distribution by type of social benefit

2.3 Disease duration period

Mean disease duration period is 10.7 years.

Table 13 Disease duration period in years (from disease onset to last visit)

Centre	Mean	Median	Minimum	Maximum	SD	Number of missing values
All centres	10.7	9.0	0.1	47.0	7.8	4

2.4 Degree of damage

Degree of damage is assessed using EDSS (Expanded Disability Status Scale) assigned value at each visit. Degree of damage is analysed as that found at the last available patient visit.

EDSS ranges from 0 to 10, where 0 means patient without complaints, degree 5 corresponds to considerable damage, inability to work and ability to walk for a distance less than 500 metres, and degree 10 means death due to MS.

Median EDSS value is 2.0. Most patients are in the 1.5–2 EDSS group.

Table 14 Degree of damage (EDSS value) at last visit

Centre	Mean	Median	Minimum	Maximum	SD	Number of missing values
All centres	2.7	2.0	0.0	8.5	1.5	6

Table 15 Degree of damage (EDSS value) at last visit

EDSS	All centres	
	Number	Percentage*
0 – 1	1352	14.1%
1.5 – 2	3437	35.9%
2.5 – 3	1718	17.9%
3.5 – 4	1409	14.7%
4.5 – 5	868	9.1%
5.5 – 6	543	5.7%
6.5 – 7	221	2.3%
7.5 – 8	24	0.3%
8.5 – 9	5	0.1%
9.5 – 10	0	0.0%

* 0.1% patients had no data completed about EDSS degree

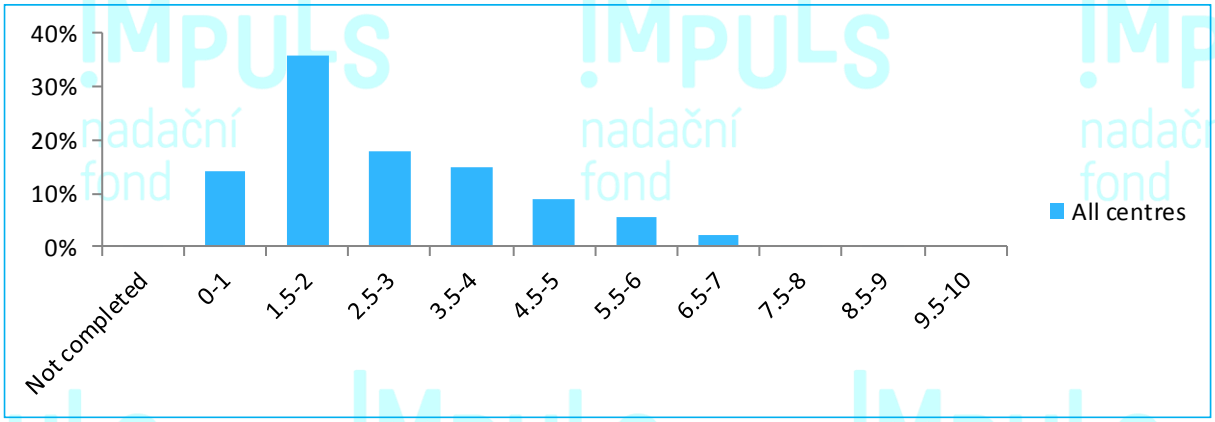

Figure 9 Patient distribution by EDSS degree

2.5 Relapse

Over the last 6 months, relapse of the disease (recurrence of symptoms) was recorded in 8.8% of patients and 20.1% over the period of 12 months. What should be taken into account is that the number of relapses reported here is an overall number including multiple relapses in one patient. Mean number of relapses annually (ARR, annualized relapse rate) is 0.201.

Table 16 Relapse occurrence over last 6 and 12 months

Relapse	All centres	
	Number	Percentage
Over 6 months	842	8.8%
Over 12 months	1924	20.1%

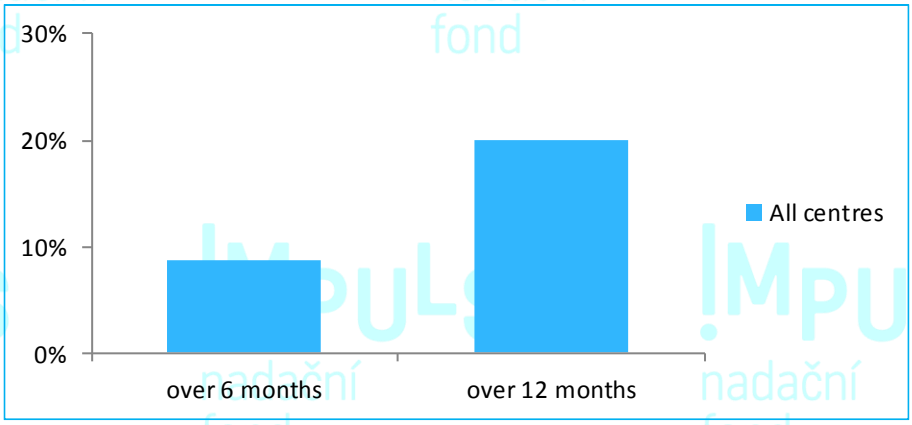

Figure 10 Proportion of relapses over last 6 and 12 months

Relapse severity is defined as mild, moderate or severe. Mild relapse intensity means that the relapse does not have negative impact on activities of daily life (ADLs). Moderate intensity relapse affects activities of daily life already, while the severe form is recorded in cases where the relapse is associated with severe discomfort of patients, deteriorates their activities of daily life significantly and results in their inability to work, or hospital admission.

Severity of most relapses was mild or moderate. Mild relapses accounted for 41.7% and moderately intensity relapses for 53.9 % over the last 6 months. Severe relapses had been recorded in 4.4% cases over the period of interest.

Table 17 Relapse severity over last 6 and 12 months

Relapse over 6 months	All centres	
	Number	Percentage
Mild	351	41.7%
Moderate	454	53.9%
Severe	37	4.4%
Relapse over 12 months	**Number**	**Percentage**
Mild	757	39.3%
Moderate	1079	56.1%
Severe	88	4.6%

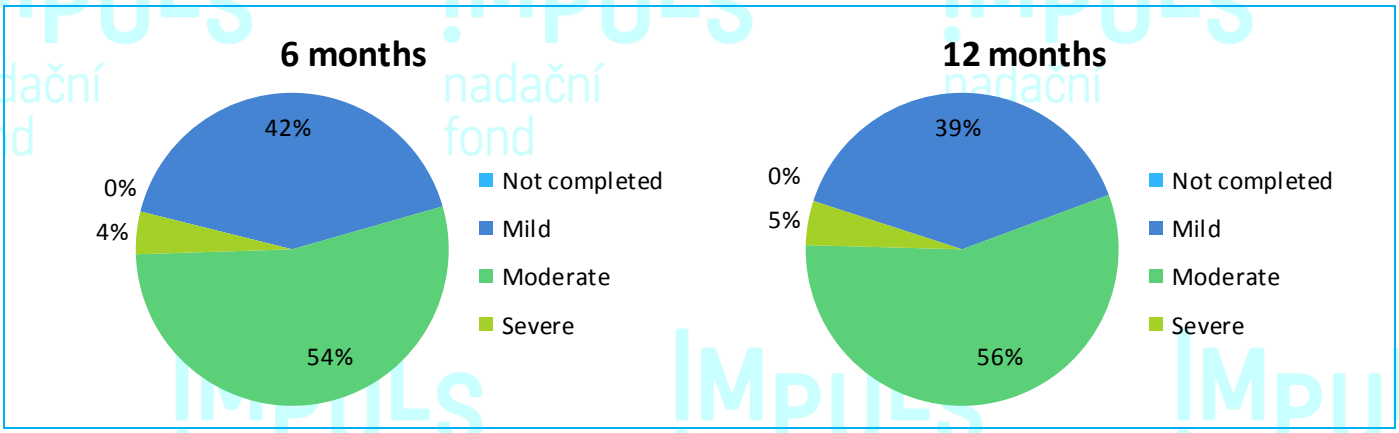

Figure 11 Relapse severity over last 6 and 12 months

The last analysed parameter was the form of relapse treatment – outpatient vs. inpatient treatment. Majority of the relapses was treated on outpatient basis. Rates of hospital treatments in individual centres were up to 10 percent.

Table 18 Type/form of relapse treatment over last 6 and 12 months

Relapse over 6 months	All centres Number	Percentage*
Outpatient	771	91.6%
Hospital stay	62	7.4%
Relapse over 12 months	**Number**	**Percentage***
Outpatient	1701	88.4%
Hospital stay	187	9.7%

* 1.1% of relapses recorded over the last 6 months data on type of treatment were missing,
1.9% of relapses recorded over the last 12 months data on type of treatment were missing

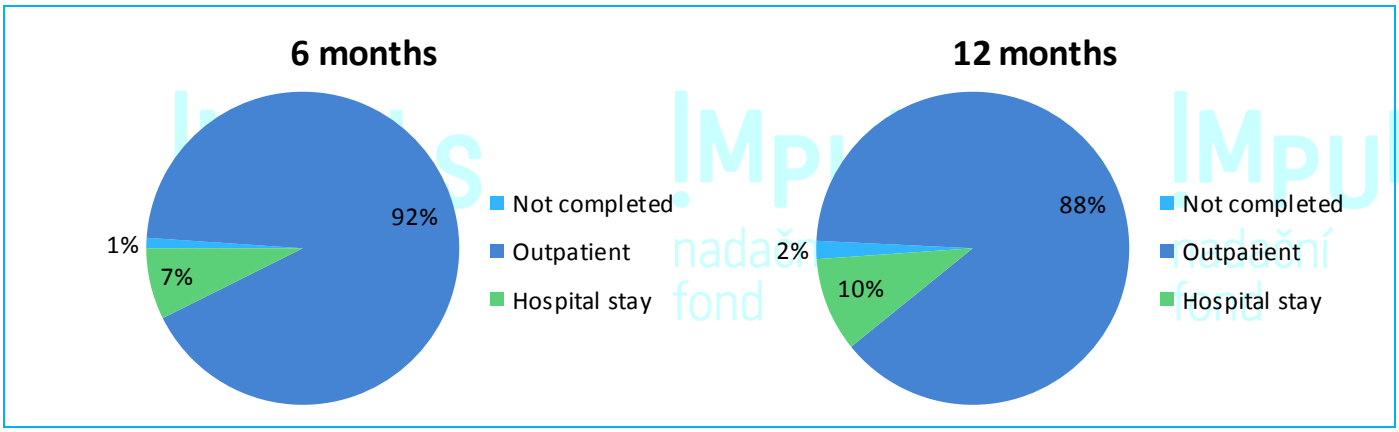

Figure 12 Type/form of relapse treatment over last 6 and 12 months

2.6 Treatment

Evaluation of MS treatment included the preparation used at last visit, a DMD or IVIG. 5 patients did not terminate their treatment for 2 preparations at the time of the last visit, so the numbers for these patients are included twice. In these cases, it is a parallel treatment with DMD and IVIG medicaments.

523 patients (5.5%) did not receive any DMD or IVIG preparation at their last visit (their treatment was temporarily or permanently discontinued). These 523 patients are not included in Table 19, but are included in Table 20.

Most patients received Copaxone (21.9%), Rebif (16.9%) and Avonex (15.1%). 27.8% of patients used the escalation therapy (Gilenya, Lemtrada, Tecfidera, Tysabri) at the time of the last visit.

Table 19 Patient distribution by the preparation used at last visit

Treatment	All centres	
	Number	Percentage
DMD		
Aubagio	494	5.4%
Avonex	1368	15.1%
Betaferon	743	8.2%
Copaxone [20]	203	2.2%
Copaxone [40]	1790	19.7%
Extavia	120	1.3%
Gilenya	1019	11.2%
Lemtrada	82	0.9%
Plegridy	114	1.3%
Rebif[22]	515	5.7%
Rebif[44]	1019	11.2%
Tecfidera	625	6.9%
Tysabri	799	8.8%
IVIG		
Flebogamma	108	1.2%
Gammagard	5	0.1%
Kiovig	48	0.5%
Octagam	13	0.1%

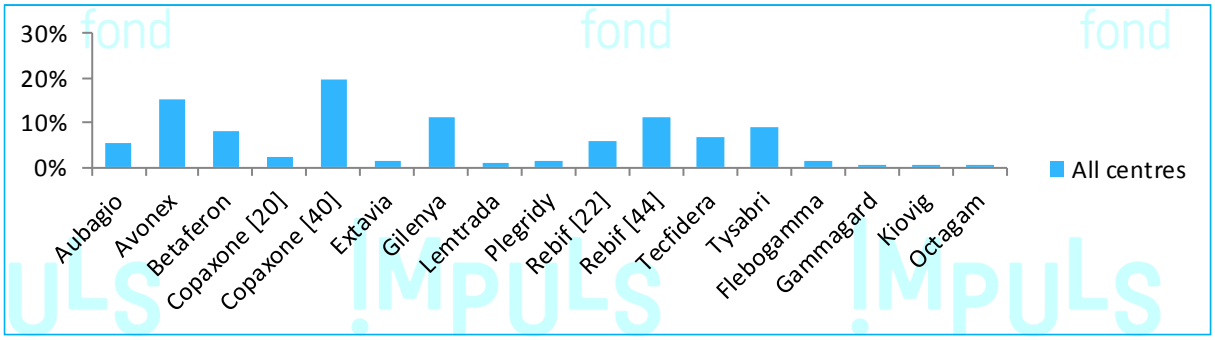

Figure 13 Medicinal preparations used - DMDs and IVIGs

2.6.1 New initiations, terminations or change of therapy with DMDs/ IVIGs

As part of a more detailed analysis of patient treatment the proportion of patients who initiated treatment with new DMD/IVIG preparations over the last half year prior to data export on 30. 6. 2017 was determined. 2.8% patients initiated treatment with these preparations.

The number of patients who terminated treatment with DMDs over the period of interest cannot be exactly determined at present. At their last visit, 523 patients (5.5%) received no treatment. 143 (1.5%) of these patients terminated/discontinued treatment over the half year of interest, and the remaining 380 patients (4.0%) had terminated treatment earlier and did not initiate new treatment over the period of interest.

The last recorded parameter was the number of patients who changed their DMD or IVIG preparation over the period of interest. The proportion of these patients was 4.9% overall.

Table 20 Number of patients who initiated new treatment with DMDs/IVIGs, terminated or changed these preparations over the period of interest

Treatment	All centres	
	Number	Percentage
Initiation	269	2.8%
New termination	143	1.5%
Earlier termination	380	4.0%
Termination overall	523	5.5%
Change	466	4.9%

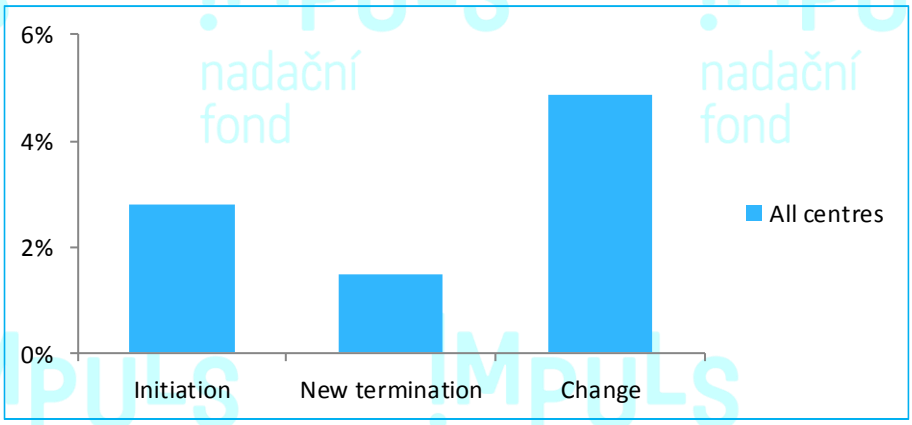

Figure 14 New initiation, termination or change of therapy with DMDs/IVIGs

2.7 Health-related events

2.7.1 Pregnancy

Over the evaluated period from 1. 1. 2017 to 30. 6. 2017 a total of 54 MS patients (0.8%) delivered children. 53 of these gave birth to 1 child. For 1 patient the number of delivered children was missing.

Table 21 Number of deliveries over the period of interest

Pregnancies	All centres	
	Number	Percentage
Number of deliveries	54	0.8%

2.7.2 Adverse events

The number of predefined adverse events was equal to 22 (0.2%) in last 6 months. Some centres had not yet started to complete this parameter in more detail. These results cannot thus be reliably interpreted so far. There is no correction in place for data expression in percentages for the case of multiple AEs in one patient.

In last 6 months there was reported no suspicion of severe or unexpected adverse event with connection to the treatment.

Table 22 Number of adverse events with first occurrence in the period of interest

Number of adverse events	All centres	
	Number	Percentage
Number of AEs	207	2.2%
Number of predefined AEs	22	0.2%
Number of severe AEs	0	0.0%

3 Results – Non-DMD patients

Data on non-DMD patients represent an integral part of ReMuS if available. Patients are classified "non-DMD" provided that they have not been administered DMD and/or IVIG either at all or only before 1. 1. 2013. Following a 2-year initial phase, each centre starts to enter additional data on these patients. In the reporting period up to 30. 6. 2017, only 2 centres were in the 2-year initial phase; University Hospital St. Anna in Brno and Regional Hospital of T. Baťa in Zlín. These 2 centres delivered information about DMD/IVIG patients only.

The centres that provided data on less than 20 non-DMD patients (University Hospital Motol in Prague, Regional Hospital Pardubice, University Hospital Královské Vinohrady in Prague, University Hospital in Brno Bohunice, University Hospital Olomouc and Hospital České Budějovice) were excluded from the analysis albeit not in the initial 2-year phase. A low sample size would not allow appropriate statistical analysis and interpretation.

Taken together, 7 MS centres were considered in the present analysis of non-DMD patients - General University Hospital in Prague (VFN), Hospital Teplice, Hospital Jihlava, University Hospital Plzeň, University Hospital Ostrava, Thomayer Hospital in Prague in Krč and University Hospital Hradec Králové. Patients were included on condition that they completed at least 1 appointment in the last year.

Table below shows the final number of non-DMD patients enrolled into the ReMuS registry up to 30. 6. 2017. The first column represents a total of all patients in the registry having signed informed consent who do not fulfil the criteria for DMD/IVIG. Number of patients whose data entered the present analysis (completed at least 1 appointment in the last year in the centre that reported more than 20 non-DMD subjects) is shown in the second column.

Table 23 Total number of non-DMD patients per centre

Centre	Non-DMD patients in the registry	Analysed Non-DMD patients (patients from centres with less than 20 non-DMD patients were not included)	Percentage of Non-DMD patients in the analysis
VFN	1038	846	42.0%
Teplice	390	375	18.6%
Jihlava	116	107	5.3%
Motol	14	-	-
Plzeň	222	212	10.5%
Pardubice	0	-	-
Ostrava	135	135	6.7%
Vinohrady	5	-	-
Krč	47	44	2.2%
Hradec Králové	314	294	14.6%
Brno Bohunice	0	-	-
Olomouc	0	-	-
Č. Budějovice	7	-	-
Total	2288	2013	100.00%

The following tables outline characteristics of non-DMD patients coming from the 7 abovementioned centres compared to DMD/IVIG patients from all 15 MS centres participating in ReMuS.

The mean age of non-DMD patients is higher than in DMD/IVIG patients (53.6 years vs. 41.6 years) and they appear to be elder at the onset of the disease (35.1 years vs. 30.9 years). Significantly smaller portion of non-DMD patients were working compared to DMD/IVIG patients which can be caused by higher age of the first group. 62.7% of non-DMD patients were not working not even part-time at the time of the last visit. There is the similar result in case of social benefits too. 39.8% of non-DMD patients were entitled invalidity pension stage 3 at the time of the last appointment, 17.7% were retired and only 26.8% of non-DMD patients were allocated no social benefits. In contrast, only 11.2% of DMD/IVIG patients were entitled invalidity pension stage 3, 2.4% were retired and 55.6% of DMD/IVIG patients did not receive any social benefits.

Table 24 Comparison of parameters of DMD/IVIG and non-DMD patients – part 1

		DMD/IVIG patients		Non-DMD patients	
Parameter		Number/Mean	Percentage/SD	Number/Mean	Percentage/SD
Sex	Female	6853	71.5%	1453	72.2%
	Male	2730	28.5%	560	27.8%
Age		41.6	10.4	53.6	11.7
Age	0 – 10	1	0.0%	0	0.0%
	10 – 20	76	0.8%	1	0.0%
	20 – 30	1277	13.3%	57	2.8%
	30 – 40	2985	31.1%	209	10.4%
	40 – 50	3176	33.1%	474	23.5%
	50 – 60	1578	16.5%	587	29.2%
	60 – 70	463	4.8%	554	27.5%
	70 – 80	27	0.3%	127	6.3%
	80 – 90	0	0.0%	4	0.2%
	90 – 100	0	0.0%	0	0.0%
Age at disease onset		30.9	9.6	35.1	11.3
Employment	PTE	1336	13.9%	156	7.7%
	FTE	5538	57.8%	593	29.5%
	DNW	2167	22.6%	1262	62.7%
	STUDENT	246	2.6%	2	0.1%
Social benefits	DP1	1305	13.6%	133	6.6%
	DP2	717	7.5%	142	7.1%
	DP3	1072	11.2%	801	39.8%
	ML	563	5.9%	31	1.5%
	UNEMPL	73	0.8%	10	0.5%
	OAP	229	2.4%	356	17.7%
	Does not receive (X)	5325	55.6%	540	26.8%
Disease duration period		10.7	7.8	18.5	10.7

Non-DMD patients in the registry have higher mean EDSS compared to DMD/IVIG patients (4.7 vs. 2.7) whilst the most frequent are those with EDSS stage 6.5–7 (23.7%). 2.0% of non-DMD patients experienced relapses in last 6 months and 5 non-DMD patients (0.2%) gave birth in last 6 months.

Table 25 Comparison of parameters of DMD/IVIG and non-DMD patients – part 2

		DMD/IVIG patients		Non-DMD patients	
Parameter		Number/Mean	Percentage/SD	Number/Mean	Percentage/SD
EDSS		2.7	1.5	4.7	2.2
EDSS	0 – 1	1352	14.1%	137	6.8%
	1.5 – 2	3437	35.9%	290	14.4%
	2.5 – 3	1718	17.9%	180	8.9%
	3.5 – 4	1409	14.7%	213	10.6%
	4.5 – 5	868	9.1%	179	8.9%
	5.5 – 6	543	5.7%	325	16.1%
	6.5 – 7	221	2.3%	478	23.7%
	7.5 – 8	24	0.3%	168	8.3%
	8.5 – 9	5	0.1%	37	1.8%
	9.5 – 10	0	0.0%	4	0.2%
Relapse occurrence over 6 months		842	8.8%	41	2.0%
Relapse occurrence over 12 months		1924	20.1%	88	4.4%
Pregnancies Last 6 months	Number of deliveries	54	0.8%	5	0.2%
Pregnancies Last 12 months	Number of deliveries	132	1.9%	8	0.4%

4 Conclusion

On 30. 6. 2017, the ninth data export into ReMuS registry was delivered, followed by interim data analysis from the registry focusing on the period from 1. 1. 2017 to 30. 6. 2017. Over the evaluated period data of DMD/IVIG patients from fifteen MS treatment centres – General University Hospital in Prague (VFN), Hospital in Teplice, Hospital in Jihlava, University Hospital Motol in Prague, University Hospital in Plzeň, Hospital of Pardubice Region, University Hospital in Ostrava, University Hospital Královské Vinohrady in Prague, Thomayer University Hospital in Prague in Krč, University Hospital in Hradec Králové, University Hospital in Brno in Bohunice, University Hospital in Olomouc, Hospital in České Budějovice, University Hospital St. Anna in Brno and Regional Hospital T. Baťa in Zlín are included. Information about non-DMD patients was provided by 7 MS centres - General University Hospital in Prague (VFN), Hospital in Teplice, Hospital in Jihlava, University Hospital in Plzeň, University Hospital in Ostrava, Thomayer University Hospital in Prague in Krč and University Hospital in Hradec Králové. These MS treatment centres are no more in the initial phase (they have been entering data for more than 2 years) and were eligible to enter the analysis by providing data on more than 20 non-DMD patients. All MS centres enter data on their patients in the registry on continual basis, and as of the day of export on 30. 6. 2017 data on the treatment of 9911 DMD/IVIG patients and 2288 non-DMD patients has been collected. After the exclusion of patients missing recent data, data of the total of 9583 DMD/IVIG and 2013 non-DMD patients from the whole Czech Republic were processed for the purpose of the present analysis.

The main analysis was performed on the data from DMD/IVIG patients. Patients in the registry are in 71.5% of cases of female gender, mean age at the last visit is 41.6 years and the mean age at the disease onset is 30.9 years. 99.7% of patients are over 18 years old at the time of the last visit. 57.8% of patients were insured with the General Health Insurance Company (VZP). The registry includes data of patients from all regions of the Czech Republic. 71.7% of patients are able to work (they work full-time or part-time) and 32.3% receive degree 1-3 disability pensions. The most frequent degree of damage impairment are patients with EDSS between 1.5 and 2. Mean number of relapses in one year (ARR, annualized relapse rate) is 0.201. More than a half of relapses over the last 6 months were of moderate severity (53.9%), and majority of patients were treated as outpatients (91.6%). Medicinal preparations used most often are Copaxone (21.9%), Rebif (16.9%) and Avonex (15.1%). 27.8% of patients used the escalation therapy at last visit. In the study period, 2.8% of patients started DMD treatment, 1.5% patients ended or interrupted the DMD treatment and 4.9% of patients changed their DMD treatment. A total of 54 MS patients (0.8%) delivered children during last 6 months. There was reported no serious adverse event connected with MS treatment within observed period.

Non-DMD patients were described in terms of demographic, working activity, social benefits, duration of the treatment, EDSS, frequency of relapses and pregnancy. Data from 7 MS centres which are contributing were processed. Non-DMD patients are elder in average compared to DMD/IVIG patients (53.6 years vs. 41.6 years) and they are also elder at the onset of the disease (35.1 years vs. 30.9 years). Significantly smaller portion of non-DMD patients are working compared to DMD/IVIG patients which can be caused by higher age of the first group. 62.7% of non-DMD patients are not working not even part-time at the time of the last visit. Non-DMD patients in the registry have higher mean EDSS compared to DMD/IVIG patients (4.7 vs. 2.7) whilst the most frequent are those with EDSS stage 6.5-7 (23.7%). 2.0% of non-DMD patients experienced relapses in last 6 months and 5 non-DMD patients (0.2%) gave birth in last 6 months.

Progressive engagement of the individual centres needs be considered for interpretation of the outcomes. The records are continuously corrected and amended based on the deviation reports in all participating centres.

Compared to the first data export in June 2013, the number of patients in the registry increased more than eight-fold while the number of missing data was reduced and with participation of new centres the variability of patients and their treatment in the Czech Republic increased.

Endowment fund IMPULS
Kateřinská 30, Praha 2, ID: 26169428
www.multiplesclerosis.cz