Could real world evidence data become the co-driver of regulatory and reimbursement decisions?

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Are long-term data on MS needed?

- Nobody knows how the course of MS has changed after introduction of DMDs
- How early versus late start of Tx influences disability
- How early versus late escalation changes the prognosis
- Disability = money (healthcare, disability pensions, loss of GDP, care in late stages, QoL)

How looks dream registry like?

- national registries using IT to co-operate and enable to join data into large databases (MSBase)
- meaningful data sets
- ensured quality of data
- financed but INDEPENDENT (physicians and patient must be proactive)
- collecting data on social situation of MS patients and working capacity
- successful examples: Swedish registry, Czech registry…

Can we trust real-life data ?

YES, IF:

- data quality is regularly checked
- motivation of those entering the data is kept
- each subject understands the meaningfulness of the registry (e.g. change in health care occurs based on the data)

= financing is solved

Czech MS Registry ReMuS

- Established 2013, data from 15 MS Centers about > 9000 pts on DMDs, using iMed
- Output twice a year, demographics, info on therapies, % of escalation therapies, info on working status
- Data owned by Foundation IMPULS, scientific board : Working group for MS (Czech Neurological Society), independent handling of data by statistical company, multisource financing

Conclusions

- Payers should act based on data from both clinical studies leading to registration of drugs AND real-world data
- Goal of treating physicians and payers and all health authorities should be the SAME:

NO DISEASE ACTIVITY, QoL including ability to work and lead independent life

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