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

Eva Havrdová
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
Acknowledgments:

Assoc. Prof. Dana Horáková, PhD
Leader of Czech MS Registry ReMuS

Team of MS Center at First Medical Faculty, Charles University

IMPULS – Foudation financing Czech Registry