EUReMS and Beyond

Opportunities and challenges for the European Network of MS Registries in 2016 -2020

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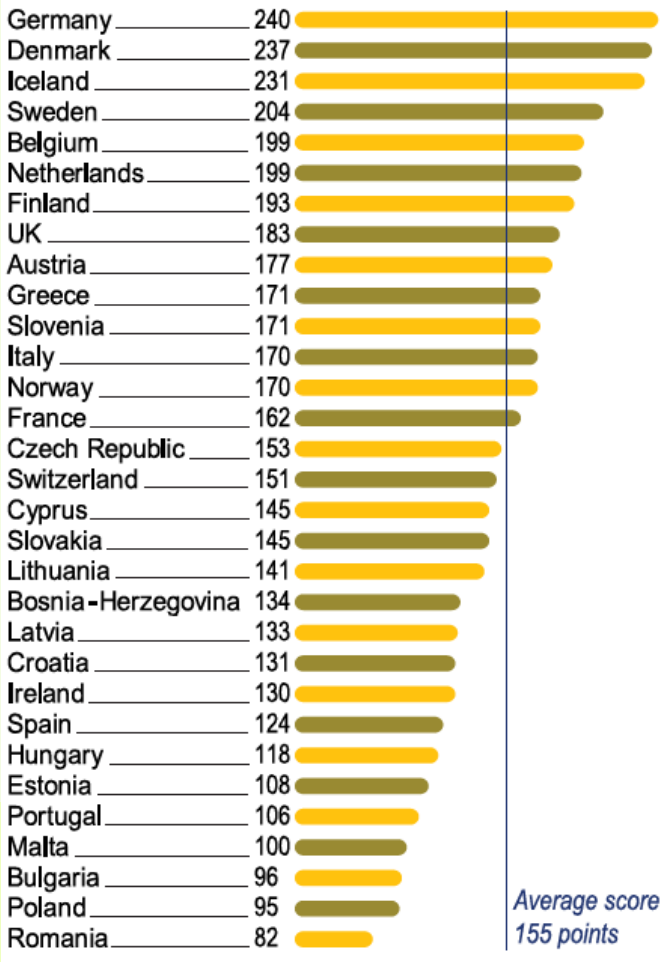
How our national data collection for analysis on European level began:

EMSP's MS Barometer – monitoring by benchmarking



How is the MS Barometer structured?

Seven priority thematic areas have been identified.The maximum score possible for each section appears in brackets.

1. Access to treatments and therapies (75 points)
2. Research agenda in MS (15 points)
3. Employment & Job retention (40 points)
4. Empowerment of people with MS (45 points)
5. Reimbursement of Costs (55 points)
6. Accurate Data Collection (25 points)
7. Medication coming to the market (15 points)

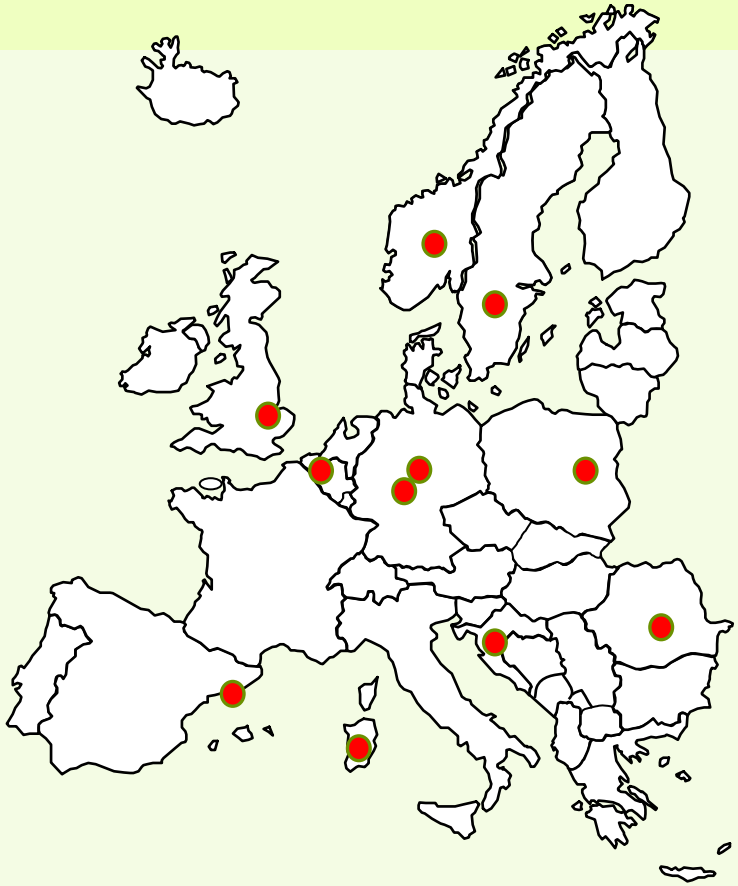
Who provides data for the MS Barometer?

The MS Barometer is completed by the national MS society in each country and endorsed by the society's Medical Advisory Board.

EUReMS project co-funded by the Health Programme 2011-2014 (European Commission, DG Sanco)

Collaborative approach to MS data: patients' representatives, Clinicians and academics

11 Project partners
incl. **5 MS Registers participating**
In 2011



Health Programme 2008-2013 Together for Health

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EUReMS missions

1. MS epidemiological and clinical surveillance across European countries, including the assessment of the 'MS burden' in Europe
2. Assessment of long-term efficacy, **safety** and cost-effectiveness of MS disease modifying and symptomatic treatments across European countries
3. Assessment of provision and quality of health care services across European countries, and
4. Assessment of PwMS' quality of life, the burden of symptoms and socio-economic aspects from the patient's perspective across European countries

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EUReMS Core data set as starting point

Item	Description
1/ Date of birth	Month, Year
2/ Sex	Female, male
3/ Disease course	Relapse-remitting Secondary Progressive Primary progressive
4/ Year of onset	First symptoms “Onset”: terminology to be defined. Suggestion: ”Year of first symptom”
5/ Year of diagnosis	
6/ McDonald criteria fulfilled	Yes/No
7/ MRI done	Yes/No
8/ CSF done	Yes/No
9/ EDSS “describing the time course”	Number Level and time (dates) so that the development can be monitored.
10/ DMD treatments	Never/past/present With date or date for 1st treatment & type of treatment.
11/ Symptomatic treatment	Never/past/present Cannot be too extensive
12/ Working	Yes/No Income generated
13/ EQ5d	5 questions
14/ MSIS-29	2 domains

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Governance of the network

- Steering Committee with 1 Rep per Registry
- Scientific Committee of KOLs as advisor
- Strong patient representation in SC
- Joint decision making with opt-out option

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RESULTS by end of 2014

- From 5 data providers in 2011 to 12 in 2014
- Model contract accepted by all data providers
- Core data set accepted by all data providers
- Four Studies completed in the fields Epidemiology, DMD effectiveness and PRO
- Socio-economic data foreseen to come from various sources

EUReMS successful as a proof of concept!

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EUReMS Project 2011-2014
Positive Outcomes

- Collaborative and geographically representative Network of MS data providers in Europe;
- Inspiration for creation of new national registries already in Poland, Czech Republic, Switzerland and the UK
- Validated procedures and methodology for MS data merging;
- IT infrastructure for pooling and analysis of (pooled) MS data at UMG;
- Ethical and legal framework for cross-border MS data analysis on the base of temporary data pooling.

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EUReMS Project 2011-2014 Limitations and Learnings

- Various interpretations of national and European **data protection law lead to delays or even drop outs**
- So far, only a **small minority** of national registries collects patient reported outcome data - despite its growing value for regulatory, pricing and reimbursement decisions
- So far, **only two registries** of the so called **BIG FIVE** have committed themselves to network cooperation
- Big **divergence of interests** among stakeholders require lots of time, diplomacy and ….funds!

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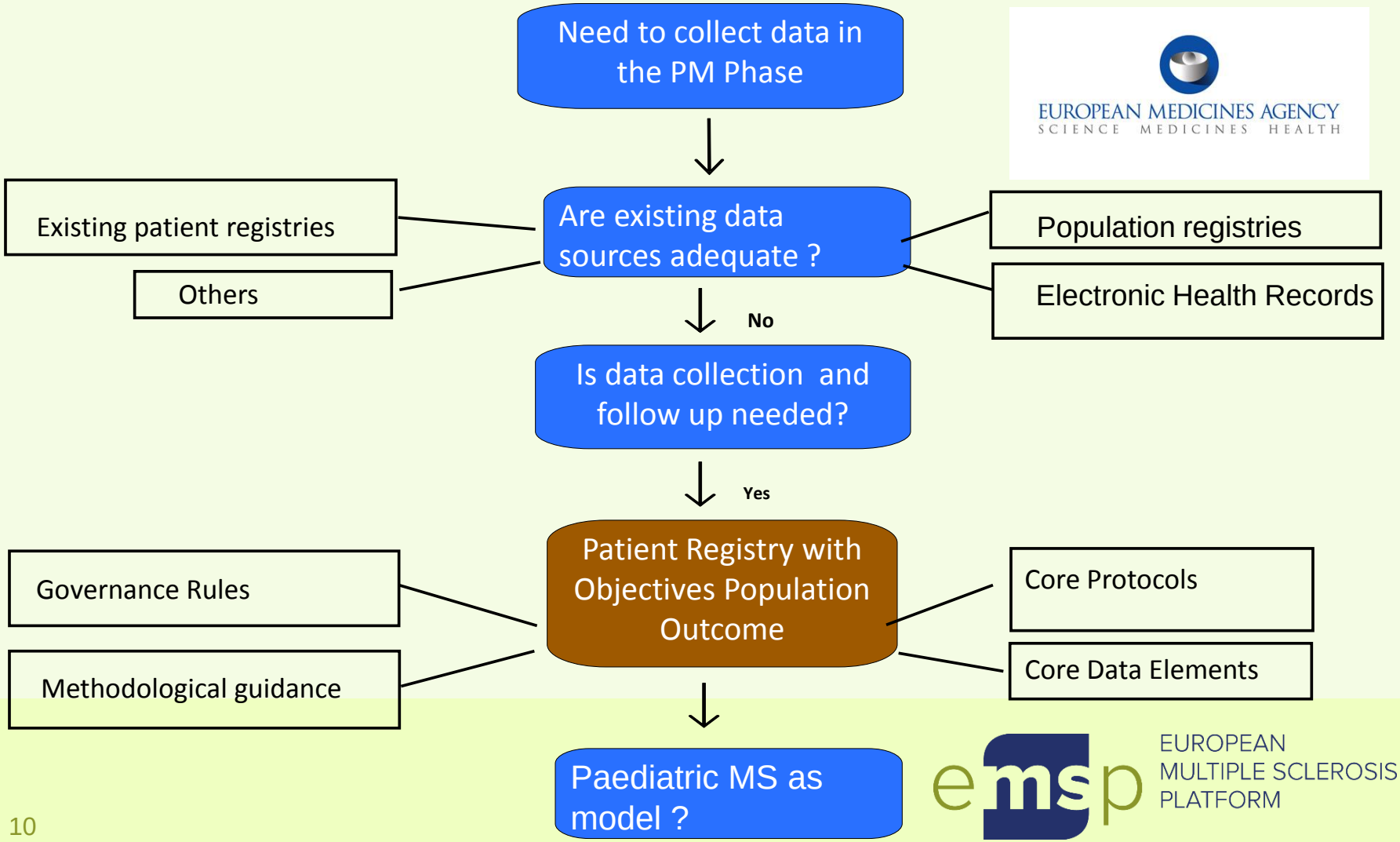
EUReMS collaboration with EMA: Cross Committee Taskforce for Patient Registries (2014-2016)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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From the “European Register for MS” to the “European Network of MS Registries”

The recently announced IMI2 call

« **Big Data for Better Health Outcomes** »(BD4BO)

could provide the opportunity to move on from EUReMS as a “proof on concept” of effective cross-border cooperation of national registries and data pooling plus centralized data analysis

towards

a European Network of MS Registries potentially becoming the nucleus of one or several project proposals within this call.

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FOR DISCUSSION: European Network of MS registries to develop ”SINGLE EUROPEAN PLATFORM FOR PATIENT RELEVANT OUTCOMES”

- Medical data alone being derived from traditional clinical trials are no longer regarded as “golden standard”, because there are not mirroring “real life” conditions, they are too expensive because the trials are too long and they rarely reflect on patient relevant outcomes

- Both clinical research and patient advocacy is longing for stronger real life evidence

- Patient Reported and Patient Relevant Outcome Data are expected to grow into a major role as second criteria for future regulatory and pricing /reimbursement decisions together with clinical data from registries and clinical trials.

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FOR DISCUSSION: European Network of MS registries to develop "SINGLE EUROPEAN PLATFORM FOR PATIENT RELEVANT OUTCOMES"

- US government funded PCOR (Patient Centered Outcomes Research Institute currently tries to identify patient registries for potential collaborative opportunities on comparative effectiveness research on MS treatment
- BUT:
- Although there are a number of PRO registers in MS on local, regional national level in Europe (e.g. Sweden, UK, Germany) and in the US (NARCOMS), no global or even European standard for PRO (x2) exists, neither for the choice of validated scales, nor for a commonly agreed core dataset.

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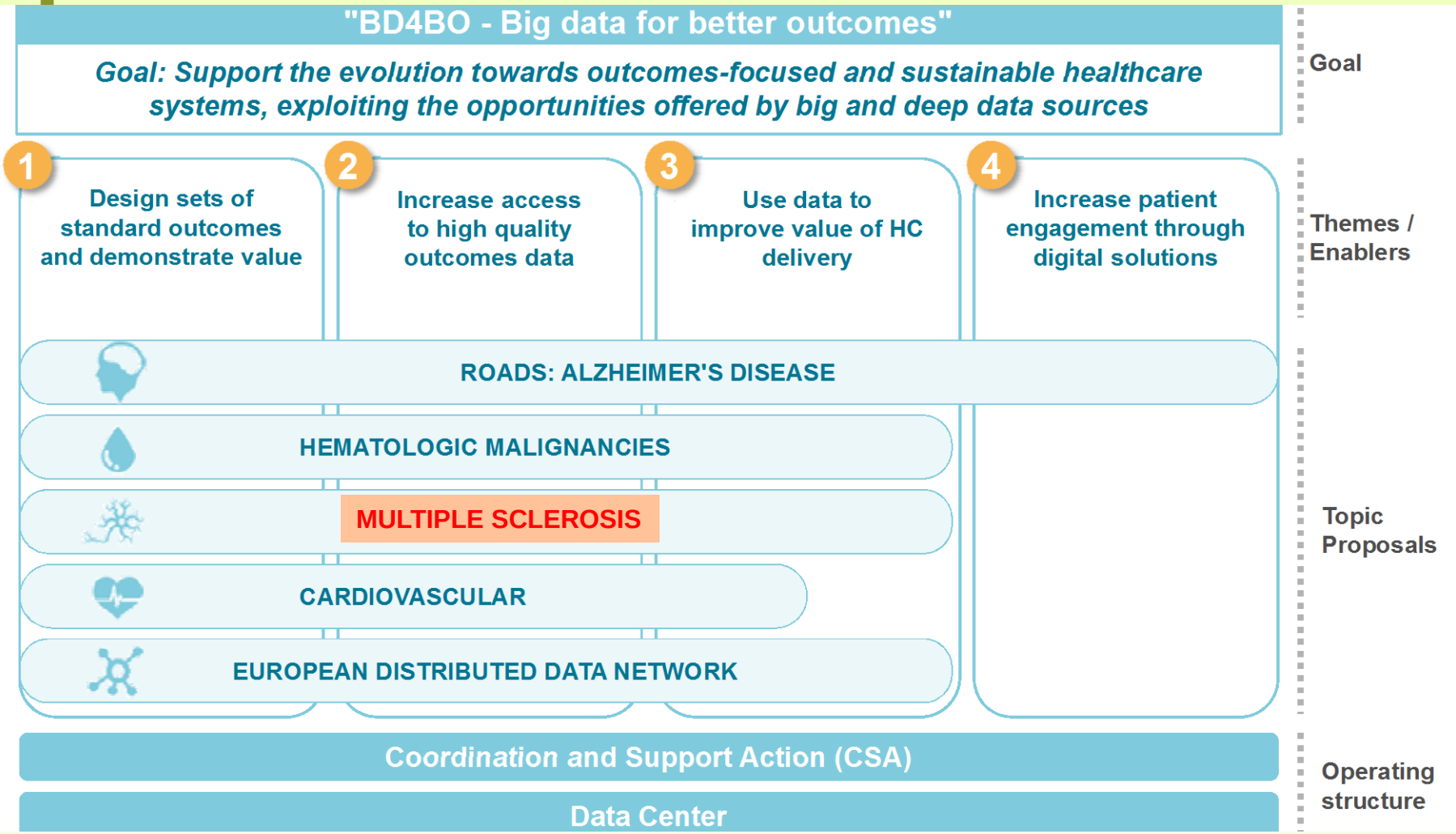

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Goal

Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by big and deep data sources

Themes/Enablers

A — Design sets of standard outcomes and demonstrate value

- Sets of target outcomes
- Clinical endpoints
- Alignment of HC stakeholders on the value of those outcomes..

B — Increase access to high quality outcomes data

- Mapping of sources, methods and tolls for collection and harmonization
- Governance and technical standards...

C — Use data to improve value of HC delivery

- Drivers of outcomes variation
- Best clinical practices
- Methodologies to predict outcomes...

D — Increase patient engagement through digital solutions

- Patient Reported Outcomes opportunities
- Profiling patients behaviors
- Tools to increase patient engagement...

FOR DISCUSSION: European Network of disease specific registries– support for regulatory tasks?

If yes – which tasks ?

- PASS
-
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If no – why not?

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