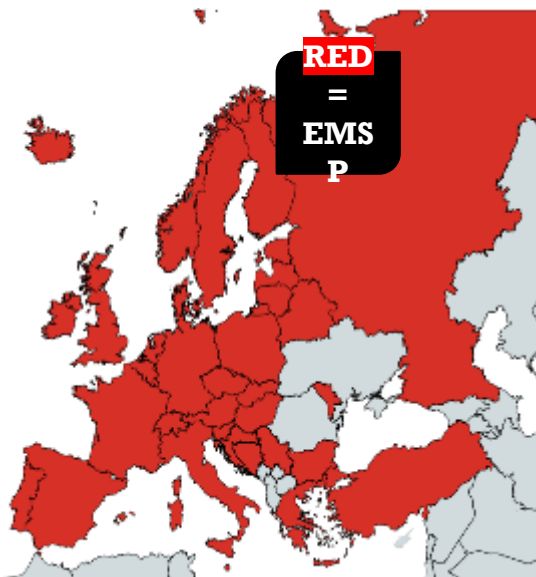


# Learnings & next steps for EMSP as initiator and driver



Over the past 5 years, up to 13 national MS registries have been working together in four studies, based on common agreements for core data sets.

Data were fed cross border into a central analysis center in Germany to produce answers to researchers' and to patient-driven questions

Better RWE through temporary data pooling: As a „proof of concept“, we already made the network of European MS registries happen through EUREMS!

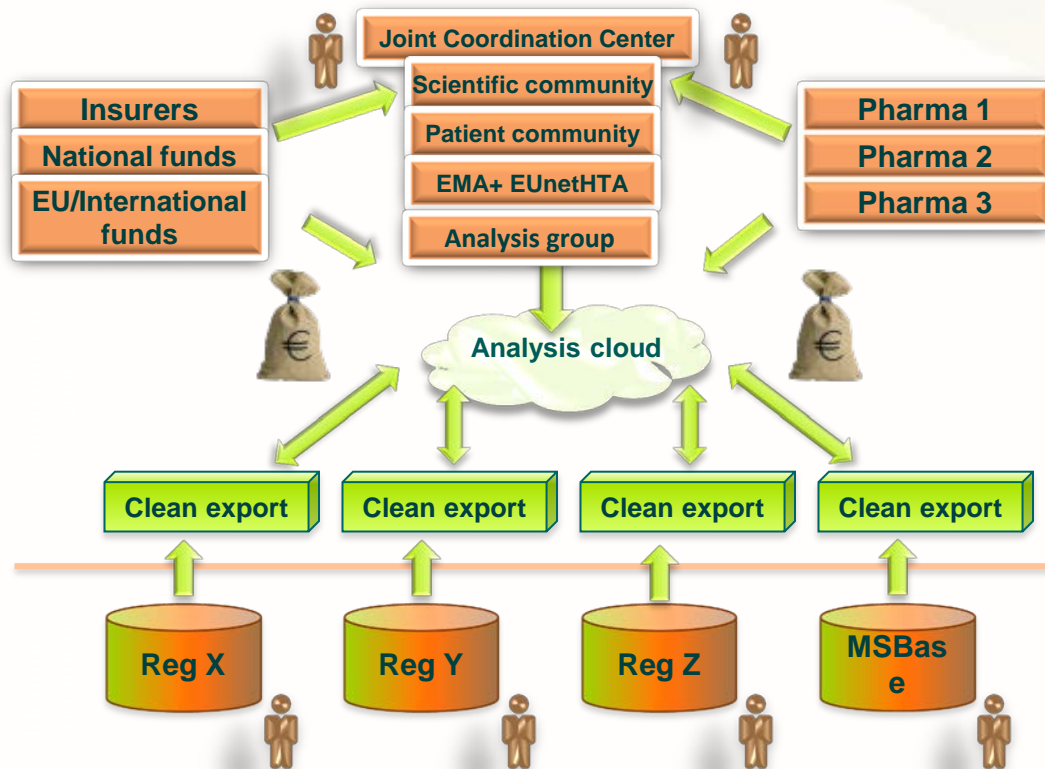
"Optimized exploitation of patient registries, cohorts and databases in Europe – Multiple Sclerosis as exemplar for patient centred & evidence based health care"

Almost  
Approved

OptiMuS

A first attempt of 18 project partners towards H2020 brought lots of learnings to be build on NOW!

Advised by EMA and EUnetHTA, we will start build MS DATA ALLIANCE as our European answer for data needs of stakeholders





## **MSIF iPROs Initiative in cooperation with EMSP**

- **To focus on ‘Patient Reported Outcome Measures (PROMs) in real world settings (after the clinical trial phase)**
- **To identify those functional domains that matter most to people with MS – with direct patient help (focus groups) as well as via a literature review (ICF<sup>1</sup>) model? COMET<sup>2</sup>) database?).**
- **To harmonize the existing PROMs globally - using the domains selected above (maybe supported by ICHOM<sup>3</sup>) )?**
- **To liaise with parallel efforts of DO-IT! – the IMI support action for Big Data projects**

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<sup>1</sup> International Classification of Functioning (working with WHO)

<sup>2</sup> Core Outcome Measures in Effectiveness Trials Initiative

<sup>3</sup> International Consortium for Health Outcomes Measurement (working with OECD)

# Key points to remember for patient organisations being active or interested in data collection

- There is a wealth of information, guidelines and good practice out there on building, structuring and harmonising patient registries: PARENT, EMA's Patient registries initiative, COMET, ICF, ICHOM and more can be used!
- PASS studies via registries being made fit for purpose is a first obvious task, but also comparative effectiveness trials for several existing therapies have started to use registry data
- Regulators's move from drug registry data to patient registry data has started and soon HTA and Payors will follow – be part of this development together with Your HCP organisation!!

# Disease registries: Patients' Perspective

Jana Hlaváčová, EMSP

London, 21 September 2017  
Eleventh stakeholder forum on the  
Pharmacovigilance Legislation



# Different Patients' Perspective

“I want to contribute with my experience with the disease to better understanding of it.”

“How can I, a single patient, help the research?”

“I do not feel safe providing data about the course of my disease.”

“I have no clue how they will use the data.”

“These collected data will serve as evidence to decision-makers in making treatment more accessible / will help to design treatment plans according to needs of patients.”

“Unfortunately, the registry holder did not consider this aspect of the disease as relevant and do not have the data to support our suggestion.”

“How can we collect the data that may not seem important to clinicians, but are relevant to patients and their quality of life?”

# Importance of data collection to the Patient

## Research

Data important to understand the disease  
Insight to possible causes, risk factors

## Practice

Health Care and Social Service Planning, Disease-management schemes

Access to treatment  
Regulatory and coverage decision-making

## Treatment results

Data on effectiveness and safety of treatment  
Benefit-risk evaluation

Information about the disease and its course

See also **The current situation, the Challenges and the Expectations on the Patient Registries and Databases. II – Results of the Patient Survey. EURORDIS, 2013:** In patients' expectations / aims of the registries according to patients, the 3 choices that received the highest preferences were: 1. Healthcare and Social Service Planning for Patients, 2. Evaluation and monitoring of efficacy/safety of disease treatment, 3. Description of the disease.

# Patients' needs in contributing to registries

## Information

- On the register and its aims
- Character of the register, right holders
- Data protection system
- Rights of participants/contributors/patients (e.g. access to data, right to withdraw etc.)
- Who has access to data and how they are used

## Informed consent

- Different legal regimes in different states, need of a minimum standard
- Patients need to understand the information provided
- Legal protection of the patient

## Data protection

- Protecting safety and confidentiality of the data
- Sufficient Security System
- Safe use of data without unnecessary risks to patients.



# Factors further increasing the willingness to contribute

## Accessibility and transparency of information and results

- Proper information policy of data collectors
- Availability of information about the use of data
- Understanding of elements of data collection relevant to the patient, e.g. safety concerns
- Availability of results / data and its analysis to patients and patient associations

## Participation

- Being a partner in the process
- Involvement of patients in setting and governance of the registries
- Patient-relevant data, possibility to voice their priorities
- Genuine wish to be useful – help oneself and the others
- Ownership

# Patient Participation in Data Collection

- Identification and collection of **patient-relevant data**.
- **Patients' insight and feedback** – focus, interpretation of data, incorporation of patient-relevant data, safeguard for not leaving out important factors to patients and their quality of life.
- Inclusion of an actor whose genuine interest is the **patients' interest** - giving patients a guarantee of safeguard of their best interest.
- Involvement of patients in setting the registries increases the probability of **accessibility and understandability** of processes to the patients (e.g. understandable informed consent, **effective dissemination of information** etc.)
- Increases the feeling of ownership, **motivates** patients to contribute to registries.
- Treating patients as partners empowers them.

# Patient Participation in Data Collection II

- Best to involve patients from the very **beginning of the development process** of the registry
- Participation in **Governing Bodies**
- **Rights in the Processes**
  - Participation in setting priorities, in deciding which data to collect
  - How the data are processed and used
  - Decisions in making data available to other subjects
  - Consultations
  - ...

# We have to make sure that patients...

- have sufficient access to information about the registry as well as the results and that this information is understandable to them
- their needs and priorities are considered in setting of the registries.
- can participate in the process of data-collection and the governance of the registries
- are safe in the matter of protection of their privacy



**THANK YOU for your attention!**