EUROPEAN REGISTER FOR MULTIPLE SCLEROSIS
A TOOL TO ASSESS, COMPARE AND ENHANCE THE STATUS OF PEOPLE WITH MS THROUGHOUT THE EU

FINAL REPORT

Chafea Project Grant Nr: 2010 12 13
Acronym: EUReMS
Author: Tsveta Schyns-Liharska, Scientific Project Coordinator
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Declaration by the project coordinator

I, as project coordinator of this project grant and in line with the obligations stated in the Grant Agreement declare that:

- The report represents an accurate description of the work carried out under this project grant for this reporting period;

- To my best knowledge, the financial statements that are being submitted as part of this report are in line with the actual work carried out and are consistent with the report on the resources used for the project and, if applicable, with the certificate of the financial statement.

- All beneficiaries, in particular non-profit public bodies, have declared to have verified their legal status. Any changes have been reported under section WP1 Coordination and project management, in accordance with the requirements of the Grant Agreement.

Name of the project coordinator:

TSVETANA SCHYNS-LIHARSKA, PhD

Signature:

.................................................................

Date:
9 December 2014
## Specification of the project grant

<table>
<thead>
<tr>
<th><strong>Project title:</strong></th>
<th>European Register for Multiple Sclerosis: a tool to assess, compare and enhance the status of People with Multiple Sclerosis throughout the European Union</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acronym:</strong></td>
<td>EUReMS</td>
</tr>
<tr>
<td><strong>Date(s) of the Project:</strong></td>
<td>2011-2014</td>
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<tr>
<td><strong>Starting date of the grant agreement:</strong></td>
<td>1st July 2011</td>
</tr>
<tr>
<td><strong>Duration of the grant agreement:</strong></td>
<td>39 months</td>
</tr>
<tr>
<td><strong>EC co-funding:</strong></td>
<td>987,198.00 EUR</td>
</tr>
<tr>
<td><strong>Priority area:</strong></td>
<td>3.3.2 Promote health - promote healthier ways of life and reduce major diseases and injuries.</td>
</tr>
<tr>
<td><strong>Sub-action:</strong></td>
<td>Neurodegenerative diseases - launch first phase of Multiple sclerosis</td>
</tr>
<tr>
<td><strong>Action:</strong></td>
<td>3.3.2.7 Prevention of major and chronic diseases and rare diseases</td>
</tr>
</tbody>
</table>
| **Main partner information and contact persons:** | European Platform for Multiple Sclerosis  
Maggie Alexander, Chief Executive  
Christoph Thalheim, Director External Affairs |
| **Partners involved in the Project (Institution, Acronym, Contact Person):** | 1. Savez društava multiple skleroze Hrvatske, AMSSC, Mrs. Danica Eskić  
2. Deutsche Multiple Sklerose Gesellschaft, Bundesverband e.V., DMSG, Mrs. Dorothea Pitschnau-Michel  
3. Università degli Studi di Sassari, NeuroSS, Prof. Maura Pugliatti  
4. Universitetet i Bergen, UiB, Prof. Myhr Kjell-Morten  
5. Fundació Institut de Recerca Hospital Universitari Vall d’Hebron, FIRHUVH, Dr. Jaume Sastre-Garriga  
6. Polskiego Towarzystwa Stwardnienia Rozsianego, PTSR, Mrs. Dominika Czarnota  
7. Asociatia Scleroza Multipla din Romania, SSMR, Mrs. Claudia Torje  
8. Multiple Sclerosis Society, MS Society, Mrs. Diane Redfern-Tofts  
9. Universitätmedizin Göttingen, Georg August Universität, UMG-GOE, Prof. Otto Rienhoff and Prof. Tim Friede  
10. Karolinska Institutet, KI, Prof. Jan Hillert  
11. Neurological Rehabilitation Center Quellenhof, NRCQ, Prof. Peter Flachenecker |
| **List of collaborating partners:** | European Federation of Neurological Associations; Federacion Espanola para la Lucha contra la Esclerosis Multiple, Savez Udruženja oboljelih od Multiple Skleroze Bosne i Hercegovine; European Committee for Treatment and Research in multiple Sclerosis (ECTRIMS), European Patients Forum, European Brain Council, European Federation of Neurological Societies |
| **Key words**       | 1. Disease registries; 2. Multiple Sclerosis; 3. Data Collection; 4. Codes of Ethics; 5. Patients registries |
Foreword

This report provides a detailed overview of the implementation of the European Register for MS (EUReMS) project.

Multiple sclerosis (MS) is a condition of the central nervous system which affects the way in which messages or signals are carried between the brain and the rest of the body. MS affects more than 700,000 people living in Europe. The condition is most commonly diagnosed in people aged 20-40 and two to three times as many women as men are affected.

MS varies in severity, from mild symptoms to a disabling condition: on average, half of those with MS lose their job within three years of diagnosis. The overall cost of MS in Europe to health and social care is estimated to be approximately 15 billion euros per year.

To date, the cause of MS is not known and it cannot be cured, but there are treatments to help patients manage the condition and its symptoms.

In order to better understand, and ultimately conquer MS, more data about the condition are needed. Following the success of a pilot project, the Multiple Sclerosis Information Dividend (MS-ID), co-funded by the European Commission under the Health Programme, which collected clinical, socio-economic, and quality of life data from six countries, the European Commission provided co-financing to support the development of the European Register for MS in 2010.

The EUReMS is a centralised source of information on many aspects of MS which have been gathered from other registers, such as those collected by hospitals, MS societies and research centres around Europe. EUReMS thus creates a cross-border partnership for the safe and effective storage, analysis, interpretation and dissemination of such data.

The most useful core data for collection from patients and clinicians about the nature, course and treatment of MS have been agreed. It is known that services available to patients vary substantially across Europe; by collecting information about, and regularly assessing these disparities, EUReMS can help to reduce them.

Furthermore, gaining a more detailed understanding of the characteristics of patients and their MS across Europe can provide new insights into the causes and course of the condition. Long-term collection of clinical data could also provide more information about the safety and the effectiveness of disease-modifying drugs than would be gathered from relatively short-duration clinical trials.

EUReMS has been developed alongside, and builds on existing national databases, with the ultimate aim of providing a comprehensive resource of collected data for research and practice for all European countries, including those that do not currently have their own.

The successful data gathering method used for this project lends itself to replication in disease areas other than MS, illustrates the feasibility and importance of finding ways to access information directly from patients about their experiences and has implications for those interested in identifying better strategies to manage public health.
Acknowledgements

We are grateful to the members of the Scientific Advisory Board for their guidance: Prof. Michel Clanet, France; Prof. George Ebers, UK; Prof. Gavin Giovannoni, UK; Prof. Ralf Gold, Germany; Prof. Dr. Eva Havrdova, Czech Republic; Dr. Gerhard Kindle, Germany; Prof. Xavier Montalban, Spain; Prof. Dr. Maria Pia Somani, Italy; Prof. Per Soelberg-Sørensen, Denmark; Prof. Dr. Maria Trojano, Italy.

We thank the EUReMS project partners who participated in the Working Groups and provided MS data for the EUReMS Studies:

- IMPULS MS Register Czech Republic;
- Tampere University Hospital Register;
- Italian MS Database Network;
- MS register of Liguria and Tuscany;
- Polish MS register (REJSM);
- The MS Register of Serbia.

EMSP Contributors

We acknowledge with gratitude the consistent involvement and input of members of the EMSP team, in particular Christoph Thalheim, Tsveta Schyns-Liharska and Elisabeth Kasilingam as well as the members of EMSP Executive Committee who supported the project with their time and expertise.

Co-Sponsors Acknowledgements:

We thank the following EMSP partners for providing the co-funding of the project: Almirall, Bayer Health Care Pharmaceuticals, Biogen Idec, Coloplast, Genzyme, Glaxo Smith Kline, GW Pharmaceuticals, Medtronic Foundation, Merck Serono, Novartis, Roche, Terumo and Teva. As an independent non-for-profit organisation, the EMSP brings these partners together under a strict code of conduct which ensures independence and transparency.
Final Publishable Executive Summary

The European Register for Multiple Sclerosis (EUReMS) aimed to establish a centralised source of information on MS in Europe and to create cross-border MS data collaboration for the safe and effective storage, analysis, interpretation and dissemination of such data. The key features of EUReMS are the collaborative approach, which builds on existing MS databases; its international perspective; and adding value by inclusion of patient-reported outcomes.

The EUReMS project is an initiative of the European Multiple Sclerosis Platform (EMSP) which started in July 2011 till September 2014.

EMSP partnered with eleven associated partners, which include clinical and academic centres and MS societies from Europe:
- Savez društava multiple skleroze Hrvatske;
- Deutsche Multiple Sklerose Gesellschaft, Bundesverband e. V.;
- Università degli Studi di Sassari;
- Universitetet i Bergen;
- Fundació Institut de Recerca Hospital Universitari Vall d'Hebron;
- Polskiego Towarzystwa Stwardnienia Rozsianego;
- Asociatia Scleroza Multipla din Romania
- Multiple Sclerosis Society, UK MS Society;
- Universitätsmedizin Göttingen, Georg-august-universität;
- Karolinska Institutet;
- Neurological Rehabilitation Center Quellenhof.

Alongside the project partners, well-known experts from the MS scientific community were identified to provide their expertise and guidance to EUReMS partners by assessing the overall quality of the project's activities and results. This Scientific Advisory Board (SAB) was updated and consulted on the progress of the project during the annual international meetings, organised by the European Committee for Treatment and Research in MS (ECTRIMS). The members of the SAB were: Prof. Michel Clanet, France; Prof. George Ebers, UK; Prof. Gavin Giovannoni, UK; Prof. Ralf Gold, Germany; Prof. Dr. Eva Havrdova, Czech Republic; Dr. Gerhard Kindle, Germany; Prof. Xavier Montalban, Spain; Prof. Dr. Maria Pia Somani, Italy; Prof. Per Soelberg-Sørensen, Denmark; Prof. Dr. Maria Trojano, Italy.

During the initial phase the EUReMS Consortium established the EUReMS vision, mission and objectives for 2011-2014 and beyond.

The key data that need to be collected with EUReMS, of interest for scientists and those with MS, have been identified and included in a "core data set".

This was followed by a mapping of existing national and regional MS databases in Europe: 23 of them were identified and 18 of those were surveyed. From those 18 registers participating in the initial survey, work was carried out with 13 to harmonise and standardise pooled data according to and agreed protocol.

Once this first data pooling exercise was complete, four test studies were conducted by the project partners in collaboration with the contracted 13 MS registers:
**EPI1-d Study**: Estimating Prevalence and Incidence of MS in Europe, coordinated by Prof. M Pugliatti;  
**EPI1-s Study**: Comparison of the effect of the month of birth across Europe, coordinated by D Ellenberger and Prof. T. Friede;  
**DMD1 Study**: Assessment of effectiveness of DMD in the treatment of people with MS across Europe, coordinated by Prof. J Hillert;  
**PRO1 Study**: Assessment of the patient’s perspective in the EUReMS, coordinated by Prof. P Flachenecker.

The studies served to test the functionality of the established EUReMS platform that includes:

- IT Infrastructure and standard operating procedures for MS data transfer, analysis and hosting at the Medical University Göttingen (EUReMS database);
- A validated legal and ethical framework for cross-border MS data processing; and
- A communication platform for MS registers and EUReMS operated by EMSP and Medical University Göttingen.

Moreover, they also addressed the EUReMS’ objectives related to analysis of specific topics of interest and concern.

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>DMD1</th>
<th>EPI1-s</th>
<th>EPI1-d</th>
<th>PRO1</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS register of Croatia</td>
<td>Croatia</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>IMPULS MS Register</td>
<td>Czech Republic</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<td>The Danish MS Registry</td>
<td>Denmark</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>Tampere University Hospital Register</td>
<td>Finland</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
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<td>Multiple Sklerose Register der DMSG</td>
<td>Germany</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Italian MS Database Network</td>
<td>Italy</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MS register of Liguria and Tuscany</td>
<td>Italy</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Norwegian MS-Registry and Bio bank</td>
<td>Norway</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
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<td>Polish MS register (REJSM)</td>
<td>Poland</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>MS Register of Serbia</td>
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<td></td>
</tr>
<tr>
<td>Catalanian MS Register</td>
<td>Spain</td>
<td>✓</td>
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<td>✓</td>
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<td>Svenska Multipel Skleros registret (SMSreg)</td>
<td>Sweden</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
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<tr>
<td>UK MS Register</td>
<td>UK</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Table 1** MS Registers and Databases that collaborated with EUReMS and signed the agreement with EMSP for data provision in 2013-2014.
The first results of the EUReMS1 Studies were presented at the ECTRIMS/ACTRIMS congress in Boston, September 2014 and will subsequently be published in several peer review journals.

To ensure the future development of the European MS register and secure additional support, the EUReMS Consortium has been working throughout the project duration in a broad collaboration with stakeholders and liaising with project partners over further studies. All EUReMS key stakeholders are committed to ensuring that the knowledge and momentum gained during the first three years of the project will be sustained and that the project continues to grow and develop for the benefit of all concerned, and in particular, for the tens of thousands of people affected by MS in Europe and beyond.

The EUReMS lays the foundation for systematic data collection and analysis. By doing so, the EUReMS project aligns with the Second Health Programme of the European Commission in terms of both priority areas and scope. The Health Programme objectives are to promote health, including the reduction of health inequalities, and to generate and disseminate health information and knowledge. It specifically included the development of the register for MS.

The EUReMS Consortium received financial support in the form of 60% co-funding from the Public Health Program of the European Commission for the Project. Co-funding was provided by the EMSP partners Almirall, Bayer Health Care Pharmaceuticals, Biogen Idec, Coloplast, Genzyme, Glaxo Smith Kline, GW Pharmaceuticals, Medtronic Foundation, Merck Serono, Novartis, Roche, Terumo and Teva.

**Peer Review Publications originating from the EUReMS project**
- K-M Myhr, MD, N Grytten Torkildsen, PhD, Survival in MS: Current Insights from International Registries and Databases, Supplement to the International Journal of MS Care, Sept. 2012, Vol. 14 Suppl. 4, p.5-10

**Scientific posters on EUReMS results**
- T Schyns-Liharska, M Pugliatti, P Flachenecker, D Pittschnau-Michel, J Hillert, T Friede and O Rienhoff, on behalf of the EUReMS Consortium: European Register For Multiple Sclerosis (EUReMS) – A tool to assess, compare and enhance the status of people with MS throughout the European Union, 2011
- P Flachenecker, K Buckow, M Pugliatti, for the EUReMS Consortium: Multiple sclerosis registries in Europe – results of a systematic survey, 2013
- P Flachenecker, K Buckow, D Ellenberger and J Hillert, for the EUReMS Consortium: Assessment of the patients’ perspective in the European Register for Multiple Sclerosis (EUReMS): Study protocol and first results of the PRO study, 2014

For more information, please visit the EUReMS Website: [www.eurems.eu](http://www.eurems.eu).
**Initial scope of the Project**

**Background and project scope**
The EUReMS project addresses the current lack of data at an EU level on treatment and care of people with MS. In doing so, the EUReMS aims to improve quality of health care and treatment and, ultimately, quality of life of people with MS throughout Europe.

**General objective of the project**
The primary EUReMS Objective is the establishment of a European wide platform for systematic collection, exchange and analysis of longitudinal data on multiple sclerosis (MS) in Europe.

**Specific objective(s) of the project**

<table>
<thead>
<tr>
<th>Specific objectives</th>
<th>WP</th>
<th>Deliverables</th>
<th>Level of achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Consensus on EUReMS vision, mission and purposes: In collaboration with the associated and collaborating partners, define the aims of the EUReMS and to facilitate data collection and analysis</td>
<td>WP1</td>
<td>D03. Report</td>
<td>Report has been finalised and published. The proposal from the WP1 leader was approved.</td>
</tr>
<tr>
<td>2. EUReMS Data Architecture: Establish a core dataset for EUReMS that can be extracted from the currently existing national and regional MS registries</td>
<td>WP2</td>
<td>D04. Report on functional MS databases in Europe and data mask for the test study of EUReMS</td>
<td>A survey was conducted among 23 registers followed by interviews with 18 of them. A report was drawn upon the results together with the &quot;Core data set for EUReMS&quot;.</td>
</tr>
<tr>
<td>3. Models for the future use of EUReMS data by patient advocates and by scientists: Develop statistical methodology and data analysis strategies that will be applicable and appropriate for studies utilising the EUReMS</td>
<td>WP3</td>
<td>D05. Summary of methodological approaches</td>
<td>Data methodology and analysis procedures were developed and agreed upon. The test phase was successful.</td>
</tr>
<tr>
<td>4. IT infrastructure of the EUReMS as a collaboration platform and</td>
<td>WP4</td>
<td>D07. Specification of SOPs for the working</td>
<td>The Study Protocols based upon the</td>
</tr>
</tbody>
</table>
dissemination platform processes of the EUReMS methodological approach
D08. Set of software tools, databases and developed within EUReMS were
development of the participating register of the EUReMS studies.

5. Governance and management of the EUReMS data input and output: Define the ethical principles, procedures and policies for establishing and operating EUReMS and to develop the appropriate tools to communicate and monitor this in an effective way

WP5 D09. EUReMS Charter Successfully achieved

6. Recruiting sustainable data providers: ensure a sustainable and a geographical representative network of high quality data providers to the EUReMS.

WP6 D10. EUReMS model contract for data providers A sustainable network of MS data providers has been developed. Most of the registers which have participated during the EUReMS project studies have agreed to continue their collaboration in the future.

Targeted groups
Direct: Associated Project Partners, Scientific Advisory Board, Collaborating Project Partners, MS Societies, MS pharma Industry, project officer
Indirect: MS patients, MS Researchers, MS Clinicians, General public.

Expected impact and outcomes of the project

Short-term Outcomes:
- A critical mass of national and regional MS centres for collaborative and sustainable European research in the field of MS;
- An IT platform for collaboration and dissemination of knowledge on MS;

Long-term Outcomes:
- Contribution to EU policies;
- Higher awareness of MS among clinicians and the general public in Europe;
- Improved knowledge and management of MS;
- Implementation of a quality management policy for diagnosis and management of MS;
- Sense of community for people affected by MS and their families.
## Deliverables of the project

### Deliverable 01

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Interim activities and financial reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Report</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M24</td>
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</tbody>
</table>
| Specific remarks on this deliverable | D01.1: First year Interim report  
D01.2: Second year Interim report |
| Can the deliverable be published at CHAFEA's project database? | Deliverable 1 is restricted to CHAFEA |

### Deliverable 02

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Final publishable report on the Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Report</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M39</td>
</tr>
<tr>
<td>Specific remarks on this deliverable</td>
<td>D02.</td>
</tr>
<tr>
<td>Can the deliverable be published at CHAFEA's project database?</td>
<td>yes</td>
</tr>
</tbody>
</table>

### Deliverable 03

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Report on definition of people with MS’ needs, minimum core and clinical data sets, identified characteristics of MS and other chronic diseases datasets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Publication</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M04</td>
</tr>
</tbody>
</table>
| Specific remarks on this deliverable | D03.1: EUReMS Consensus Statement  
D03.2: Publication |
| Can the deliverable be published at CHAFEA's project database? | yes |

### Deliverable 04

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Report on of currently functional MS databases and Data mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Publication</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M16</td>
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<tr>
<td>-------------------------</td>
<td>-----</td>
</tr>
</tbody>
</table>
| Specific remarks on this deliverable | D04.1: Publication on currently functional MS databases  
D04.2: EUReMS Core Data Set |
| Can the deliverable be published at CHAFEA’s project database? | yes |

**Deliverable 05**

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Summary of methodological approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Report and Protocols</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M12</td>
</tr>
</tbody>
</table>
| Specific remarks on this deliverable | D05: Summary of methodological approaches  
D05.1: Clinical Study Protocol (CSP) for DMD1  
D05.2: CSP for EPI1-s  
D05.3: CSP for EPI1-d  
D05.4: CSP for PRO1 |
| Can the deliverable be published at CHAFEA’s project database? | yes |

**Deliverable 06**

<table>
<thead>
<tr>
<th>Title of deliverable</th>
<th>Results on the testing of the EUReMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature</td>
<td>Publications</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M39</td>
</tr>
</tbody>
</table>
| Specific remarks on this deliverable | D06.1.a: Abstract DMD1 Study  
D06.1.b: Presentation of DMD1 at ECTRIMS 2014  
D06.2: Abstract for EPI1-s Study  
D06.3a: Poster EPI1-d Study  
D06.3.b: Presentation at ECTRIMS 2014  
D06.4a: Poster PRO-1 Study  
D06.4.b: Presentation of PRO1 at ECTRIMS 2014 |
| Can the deliverable be published at CHAFEA’s project database? | yes |

**Deliverable 07**

<p>| Title of deliverable | Specification of SOPs for the working processes |</p>
<table>
<thead>
<tr>
<th>Deliverable 08</th>
<th>Set of software tools, data bases, and reports documented in a standard format and CDISC format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of deliverable</td>
<td>Set of software tools, data bases, and reports documented in a standard format and CDISC format</td>
</tr>
<tr>
<td>Nature</td>
<td>Websites and servers, reports and snapshots</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M28</td>
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</tbody>
</table>
| Specific remarks on this deliverable | D08.1: EUReMS IT Structure  
D08.2: Screenshot of the export interface  
D08.3: EUReMS instructions for data transfer  
D08.3.a: EUReMS Import Framework, example DMD1  
D08.3.b: EUReMS Import Framework, example EPI1  
D08.3.c: EUReMS Import Framework, example PRO1 |
| Can the deliverable be published at CHAFEA’s project database? | Deliverables 8 are restricted to EUReMS and collaborating partners |

<table>
<thead>
<tr>
<th>Deliverable 09</th>
<th>EUReMS Charter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of deliverable</td>
<td>EUReMS Charter</td>
</tr>
<tr>
<td>Nature</td>
<td>Publication</td>
</tr>
<tr>
<td>Delivery date to CHAFEA</td>
<td>M16</td>
</tr>
<tr>
<td>Specific remarks on this deliverable</td>
<td>-</td>
</tr>
<tr>
<td>Can the deliverable be published at CHAFEA’s project database?</td>
<td>yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverable 10</th>
<th>EUReMS model contract for Data Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of deliverable</td>
<td>EUReMS model contract for Data Providers</td>
</tr>
<tr>
<td>Nature</td>
<td>Template documents</td>
</tr>
<tr>
<td><strong>Delivery date to CHAFEA</strong></td>
<td>M16</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----</td>
</tr>
</tbody>
</table>
| **Specific remarks on this deliverable** | D10.1: EUReMS Agreement with data providers  
D10.2: EUReMS data hosting contract |
| **Can the deliverable be published at CHAFEA's project database?** | yes |
Project implementation

The EUReMS project developed according to the planning detailed in Annex I without encountering any substantial difficulties in the implementation of the initial planning. An extension of the project duration was required in order to allow optimal dissemination of project results, namely to present the first results from the usage of the EUReMS database at the ECTRIMS/ACTRIMS congress in Boston, USA, 9-11th September 2014. The European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual congresses are the largest international MS scientific meetings. The 2014 event was jointly organised by ECTRIMS and its American counterpart ACTRIMS, thus becoming the largest MS event of the year and presenting a unique opportunity for the EUReMS project to disseminate its results to the wide MS scientific community and industry gathering in Boston this year.

WP1. Consensus on EUReMS’ purposes, mission & vision (M01-M04)

- During the kick-off meeting, held in Luxembourg, on the 4th July 2011, a Working Group within the WP1 was set up to draft the statement on the EUReMS’ purposes, mission & vision;
- Stakeholders’ representatives were identified and invited to the Consensus meeting that was organised at the opening day 19 October 2011 of ECTRIMS, in Amsterdam.
- At the Consensus meeting, consecutive consultations on the statement on EUReMS’ purposes, mission & vision were held with the EUReMS Steering Committee, the Scientific Advisory Board and other stakeholder’s representatives.
- At the EUReMS Steering Committee meeting in December 2011 (M6) adopted the final draft of the EUReMS Consensus statement (D03.1).

WP2. Identification and characterisation of MS registers in Europe (M04-M16)

- National and regional MS registers and databases have been continuously mapped throughout the whole duration of the project by literature searches, from information gathered through the EMSP project MS Barometer 2011, through enquiries and contacts with MS societies in Europe and through professional contacts of project partners (Overview in Table 1).
- As part of the project plan under WP2, between July 2011 and May 2012, detailed information on the organisation, the structure, and the content of the MS databases was gathered from the identified MS registries via surveys, telephone interviews with the Registry Leaders and on-site visits. Twenty-five MS registers received the standardised questionnaire and eighteen of these completed the Survey. Seven of the eighteen Survey responders were interviewed in order to obtain further details.
- The WP 2 group undertook an on-site visit to the UK MS register, Swansea, UK.
- The results from the EUReMS Survey were presented at ECTRIMS 2013 Copenhagen, and published in the peer-reviewed journal Multiple Sclerosis 28 April 2014 (D04.1).
- From May 2012 to 2013, seven additional MS registers were identified through the professional contacts of the EUReMS project participants and five of these were recruited for implementing the EUReMS studies.
<table>
<thead>
<tr>
<th>MS REGISTERS and DATABASES</th>
<th>Replied before May 2012</th>
<th>Include MS data for EUReMS objectives</th>
<th>Surveyed in EUReMS Studies</th>
<th>Inclusion in EUReMS Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurological Society of Austria MS database</td>
<td>yes</td>
<td>no¹</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Catalanian MS Register</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s, EPI1-d</td>
</tr>
<tr>
<td>Croatian MS Society Register</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s</td>
</tr>
<tr>
<td>Danish MS Register</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no⁴</td>
</tr>
<tr>
<td>EDMUS, France</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Multiple Sklerose Register der DMSG</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s, DMD1, PRO1</td>
</tr>
<tr>
<td>The Greek MS Society register</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Icelandic MS database</td>
<td>yes</td>
<td>no²</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Norwegian MS-Registry and Biobank</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s, EPI1-d</td>
</tr>
<tr>
<td>SMSreg – Svenska Multipel Skleros registret</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s, EPI1-d, DMD1, PRO1</td>
</tr>
<tr>
<td>UK MS Register</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>EPI1-s, EPI1-d, PRO1</td>
</tr>
</tbody>
</table>

**MS databases identified by MS barometer 2011**

**MS databases identified by literature**

| Italian MS Database Network | yes | yes | yes | EPI1-s, EPI1-d, DMD1 |

**MS databases identified enquiring MS Societies**

<p>| Belgian MS Society | no | - | - | - |
| Belarussian MS Society | no | - | - | - |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>Organization Name</th>
<th>EPI1</th>
<th>EPI1-s</th>
<th>EPI1-d</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Bosnia &amp; Herzegovina Udruženje obolj -elih od multiple skleroze Tuzla</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>16</td>
<td>MS Society Foundation Bulgaria</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>17</td>
<td>Czech Republic MS Center in Teplice</td>
<td>yes</td>
<td>no</td>
<td>-</td>
</tr>
<tr>
<td>18</td>
<td>Estonian MS Society</td>
<td>yes</td>
<td>no</td>
<td>-</td>
</tr>
<tr>
<td>19</td>
<td>Finnish MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>20</td>
<td>Hungarian MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>21</td>
<td>Irish MS Society</td>
<td>yes</td>
<td>no</td>
<td>-</td>
</tr>
<tr>
<td>22</td>
<td>Latvian MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>23</td>
<td>Lithuanian MS Union</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>24</td>
<td>MS Society of Luxembourg</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>25</td>
<td>MS Society of Malta</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>26</td>
<td>Dutch MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>27</td>
<td>MS Society of Portugal</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>28</td>
<td>All Russian Public Organization (RPO) of Disabled PwMS</td>
<td>yes</td>
<td>no^3</td>
<td>yes</td>
</tr>
<tr>
<td>29</td>
<td>Serbian MS Society</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>30</td>
<td>Slovakian MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>31</td>
<td>Slovenian MS Society</td>
<td>no</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>32</td>
<td>Swiss MS Society</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

**MS registers identified through project partners after May 2012**

<table>
<thead>
<tr>
<th>No.</th>
<th>Register Name</th>
<th>EPI1</th>
<th>EPI1-s</th>
<th>EPI1-d</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>ReMuS, Czech Republic</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>34</td>
<td>Liguria Regional MS Register</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>35</td>
<td>Tuscany Regional MS Register</td>
<td>-</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
List of common items that can be extracted from the existing MS registers

A common dataset of 14 Items could be extracted from the surveyed MS registers in Europe. This “Core EUReMS data set” (D04.2) can be utilised to fulfil the EUReMS objectives.
WP3. EUREMS IT infrastructure: developed and managed by the project partner
Universitätsmedizin Göttingen

✓ EUREMS Collaboration Platform (M01-M06)
To facilitate communication and collaboration among the project participants, a Microsoft
SharePoint Server was established at the Universitätsmedizin Göttingen (D07.1).
The roles and responsibilities of the users, and the processes for the usage of the
Platform were defined (D07.2) in consultation with the project partners. The EUREMS
platform can be accessed via the link https://fportal.mi.med.uni-goettingen.de/EUREMS.
The Platform will be maintained by UMG-GOE and updated by EMSP for two additional
years after the end of the project on 30 September 2014.

✓ Establishing of the EUREMS database (M06-M28)
A set of software tools for processing of EUREMS data was developed using the secuTrial
database system by the UMG-GOE, thus establishing the EUREMS database.
Standard Operating Procedures (SOPs) specifying the general processes for the usage of
the database are available at the UMG-GOE (in German) and cover:
1) The setup of the case report forms in secuTrial;
2) EUREMS specific customisation;
3) User management;
4) Export documentation;
5) Failure management,
6) Maintenance and system administration;
7) Handling and testing of software update; and
8) Long-term archiving of data.
The EUREMS database has been fully functional since May 2013 (M23) and operates
following the national regulations and the UMG-GOE data policy. After the completion of
the EUREMS-1 studies and with the agreement of the Studies Working Groups
members, EUREMS data will be archived at UMG-GOE for 10 additional years, according to the
national data regulations.

WP5. Governance and management of EUREMS data input and output (M06-
M16)
A draft proposal for EUREMS governance was presented by the WP5 Leader and
discussed with the EUREMS partners at the EUREMS workshop held in Barcelona, in May
2012 (M11). The draft EUREMS governance charter was further developed in consultation
with the appointed advisor and amended at the EUREMS meeting held afterwards.
The final EUREMS Charter (D09), that states guiding principles for MS data collection and
usage, was presented at the EUREMS meeting held in Lyon, in October 2012 (M16).

WP5. EUREMS legal framework (M01-M18)
Under the principles established by the EUREMS Charter, EMSP has drafted a Model
Contract with Data Providers (D10.1) and Agreement for Hosting of EUREMS data
(D10.2). Legal experts and EUREMS partners were consulted on the drafts, which were
then validated by the identified potential EUREMS data providers. Thirteen MS registers
participating in the EUREMS 2013-2014 Studies (Table 1) signed contracts with EMSP.
The agreement for hosting of EUREMS data was validated and signed by
Universitätsmedizin Göttingen and EMSP.

WP6. Recruiting MS data providers (M01-M39)
Throughout the entire duration of the project, efforts were made by all partners to identify, map and recruit data providers for EUReMS. More specifically, this included organisation of the project meetings in conjunction with the ECTRIMS annual congresses, presentations of EUReMS project at various conferences and forums, organisation of stakeholder’s meetings and visits to MS data sites. As a result, a high number of recruited MS registers participating in EUReMS studies during the project period was achieved, in excess of the 10 MS databases originally intended. (Annex I).

**WP4. Testing and validation of EUReMS database: EUReMS1 Studies (M15-M39)**

**EUReMS studies**

To prepare testing of the EUReMS database, the WPs Leaders held an extraordinary working meeting in Frankfurt on 13 September 2012 (M15) where an agreement was reached on:

1) How to define the research questions that will be addressed during the EUReMS test phase;
2) How to define the sources for data collection;
3) What will be the methodology applied;
4) What procedures and timelines will be followed for the EUReMS test phase.

The proposal of the EUReMS WPs Leaders was presented and discussed by the EUReMS project partners at their 3 consecutive meetings, in Lyon 10 October 2012 (M16), Frankfurt 31 January 2013 (M19) and London 8 May 2013 (M23). As a result, it was decided that four Studies would be conducted under the EUReMS:

- **EPI1-d**: Estimating Prevalence and Incidence of MS in Europe.
- **EPI1-s**: Comparison of the effect of the month of birth across Europe.
- **DMD1**: Assessment of effectiveness of DMD treatment for PwMS in EUReMS.
- **PRO1**: Assessment of people with MS’ quality of life, the burden of disease and influence of employment from the patient’s perspective across European countries.

**Studies’ concept**

The Studies were set up to address the four EUReMS missions:

- MS epidemiological and clinical surveillance across European countries, including the assessment of the ‘MS burden’ in Europe.
- Assessment of long-term efficacy, safety and cost effectiveness of MS disease modifying and symptomatic treatments across European countries.
- Assessment of provision and quality of health care services across European countries.
- Assessment of the quality of life of people with MS, the burden of symptoms and socio-economic aspects from the patient’s perspective across European countries.

The EUReMS studies’ concepts were presented to the EUReMS Scientific Advisory Board and to Stakeholders at the Second EUReMS Consensus meeting, held as planned in conjunction with ECTRIMS 2013, on 2nd October 2013 (M28), in Copenhagen.

**Studies’ organisation**

Four Working Groups, corresponding to each of the EUReMS Studies, were set up to include project partners and representatives from the participating MS registers:

- EPI1-d, chaired by D. Ellenberger and Prof. T. Friede, UMG-GOE;
- EPI1-s, chaired by Prof M. Pugliatti, NEUROSS-IT;
- DMD1, chaired by Prof J. Hillert, KI-SE;
- PRO1, chaired by Prof. P. Flachenecker, NRCQ-DE.
The WGs Chairs drafted Clinical Study Protocols (CSP) for the specific Study (D05.1-D05.4) that have been reviewed and agreed by the WG’s participants. Coordination of the WGs was ensured by the project’s Scientific Coordinator.

Launch of the EUReMS1 studies (M30-M36)
Upon the consultation with the Scientific Advisory Board and Stakeholders at the Second Consensus meeting, the test phase of the EUReMS data base was launched in M30. This effectively included the following main steps towards EUReMS data integration and analysis:

- Formal dataset descriptions of each participating MS register:
  fingerprinting of the participating MS data bases;
- Import Framework: a Guide to each data provider and participating MS registers for data provision for each study;
- receiving EUReMS Study Test datasets from each participating MS register;
- receiving EUReMS Study Productive data sets from each participating MS register
- Data Export.

Data analysis of integrated MS data and results from the EUReMS1 Studies (M30-M39)

<table>
<thead>
<tr>
<th>EUReMS study</th>
<th>DMD1</th>
<th>EPI1-d</th>
<th>EPI1-s</th>
<th>PRO1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of MS cases</td>
<td>15,788</td>
<td>13,004</td>
<td>61,848</td>
<td>4,507</td>
</tr>
<tr>
<td>Croatia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>■</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>■</td>
<td></td>
<td></td>
<td>■</td>
</tr>
<tr>
<td>Italy</td>
<td>■</td>
<td></td>
<td>■</td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td></td>
<td>■</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td></td>
<td></td>
<td>■</td>
<td></td>
</tr>
<tr>
<td>Serbia</td>
<td>■</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td></td>
<td>■</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
</tr>
</tbody>
</table>

Table 3: Integrated MS data for EUReMS1: Number of MS cases from 10 participating countries (11 MS databases).

The first results of the EUReMS1 Studies were presented (D06.1-D06.4) at the ECTRIMS/ACTRIMS congress in Boston, September 2014 and will subsequently be published in several peer review journals.

Coordination with other projects or activities at European, National and International level

EUReMS Main and Associated Partners liaised with various other activities at European, National and International level related to MS data collection. EUReMS has been invited and its representatives actively participated in the following major EU funded projects:

- The PARENT Joint Action (Cross Border Patient Registries Initiative) - as member Associated Projects Group (APG) represented by C. Thalheim, Prof. T. Friede, Dr. T. Schyns-Liharska and E. Kasilingam.
The EUReMS Charter and Model Contract for DPs have been shared with and acknowledged by PARENT JA as Good Practice for Cross Boarder registries.

- **The EUnetHTA Joint Action 2** – in the Stakeholder Forum meetings and teleconferences, represented by C. Thalheim and Dr T. Schyns-Liharska.

**Sponsorship**

Sponsorship of the EUReMS project was provided to EMSP under a strict code of conduct which ensures independence and transparency by Almirall, Bayer Health Care Pharmaceuticals, Biogene Idec, Coloplast, Genezyme, Glaxo Smith Kline, GW Pharmaceuticals, Medtronic Foundation, Merck Serono, Novartis, Roche, Terumo and Teva.
Project Coordination (WPH1)
The coordination of the project was provided by the EMSP team that included Christoph Thalheim for the overall project management and co-sponsorship, E. Kasilingam for financial, event and communication management and Dr. T. Schyns-Liharska for scientific coordination.

Partnership management
At the kick off meeting, the Scientific Coordinator presented to the project partners the first draft of the project Terms of References (TR), Appendix 1. The document defines the roles and the responsibilities of the project partners and the process for management of tasks and achievements of the project. The TR had been updated during the course of the project according to the decisions agreed upon by the Steering Committee. Intellectual Properties issues on the exploitation of the Studies’ results have been detailed in the CSPs.

Project Management
The governance body of the EUReMS is the Steering Committee (SC) comprised of representative(s) of each partner organisation. Face-to-face meetings of the SC were organised at each of the project meetings (see list of meetings, Table 4).
From M03 on, the management team started to organise regular videoconferences via an online system, Webex, with the SC. This dramatically enhanced the internal SC communication as well as the monitoring and supervision of the project activities. In total, 18 Webex teleconferences were held (Minutes of the TCs are included in the Appendix 2).

During the Test phase of the EUReMS databases (M25-M39) Webex teleconferences were organised for the Studies WGs by the Scientific Coordinator.

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Date, place</th>
<th>Number of participants</th>
<th>Appendix document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kick off meeting</td>
<td>3-4 July 2011, Luxembourg, Lx</td>
<td>18</td>
<td>Agenda; List of participants; Minutes- Appendix 3</td>
</tr>
<tr>
<td>First Consensus meeting</td>
<td>19 October 2011, Amsterdam, NL</td>
<td>88</td>
<td>Agenda; List of participants; Minutes- Appendix 4</td>
</tr>
<tr>
<td>EUReMS project meeting</td>
<td>21-22 May 2012, Barcelona, ES</td>
<td>36</td>
<td>Agenda; List of participants; Minutes- Appendix 5</td>
</tr>
<tr>
<td>WP Leaders working meeting</td>
<td>13th September 2012, Frankfurt, DE</td>
<td>10</td>
<td>Agenda; List of participants; Minutes- Appendix 6</td>
</tr>
<tr>
<td>Additional meeting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Workshop</td>
<td>10th October 2012, Lyon, FR</td>
<td>24</td>
<td>Agenda; List of participants; Minutes- Appendix 7</td>
</tr>
</tbody>
</table>
Workshop (meeting initially planned in May, in Göttingen) 31 January 2012, Frankfurt, DE 20 Agenda; List of participants; Minutes- Appendix 8
Workshop Additional meeting 8 May 2013 London, UK 22 Agenda; List of participants; Minutes- Appendix 9
Second Consensus meeting 2 October 2013, Copenhagen, DK 44 Agenda; List of participants; Minutes- Appendix 10
Final Project meeting Additional meeting 10 June 2014 Brussels, BE 20 Agenda; List of participants; Minutes- Appendix 11.

Table 4 EUReMS Project meetings and workshops.

No changes in the partnership, nor to the legal status of any of the beneficiaries occurred during the time of the project.

Subcontracting of external evaluator, of communication consultant, of external PR, of legal advisor, of health economy consultant and for printing materials have been done by five project partners, namely EMSP, SSMR, PTSR, UK MS Society and KI according to their applicable rules.

Financial management
The project financial management was undertaken by EMSP as the main beneficiary. During the course of the project, EMSP monitored implementation of the activities and the budget according to the Project grant agreement.

Three instalments from the European Commission were received as follows:

12/03/2012 – 296.159,40 EUR
26/10/2012 – 197.439,60 EUR
27/09/2013 – 197.439,60 EUR

The received instalments were transferred in accordance with the initial budget planning to each of the beneficiaries.

Interim financial reports were provided to the European Commission in accordance with the grant agreement.

During the course of the project, two amendments were requested to adapt the project budget to the development of the organisation and the modification in implementation of the activities and needs.

The final budget shows that more than 10% of the estimated budget has not been used (see table below).
<table>
<thead>
<tr>
<th>Items</th>
<th>Estimated budget</th>
<th>Real expenditure</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2. Travel costs and subsistence allowances</td>
<td>96.122,16 EUR</td>
<td>73.595,69 EUR</td>
<td>Although all the planned meetings took place together with additional meetings, the travel budget has not been fully used. This can be explained by the fact that some partners could not attend all the meetings and that combining the events allowed a reduction in the costs. In addition, the use of the Webex system to have monthly teleconferences with the Steering Committee has been beneficial in helping to reduce the need for face-to-face meetings between the Partners as well as with external stakeholders.</td>
</tr>
<tr>
<td>E5. Subcontracting costs</td>
<td>136.964,00 EUR</td>
<td>65.837,57 EUR</td>
<td>The budget planned for consultancy on existing registers and non EU data sets was used to a more limited extent than originally planned as through the extensive and detailed survey ran within the WP2, we were able to acquire the required information and initiate close collaboration with the existing MS registries in EU.</td>
</tr>
<tr>
<td>E6. Other costs</td>
<td>93.616,44 EUR</td>
<td>32.890,62 EUR</td>
<td>Combining the main project meetings with main events gathering experts in the field of MS such as the EMSP annual conference or ECTRIMS/ACTRIMS annual congress allowed not only a greater participation of the experts to the EUReMS meetings but also a reduced number of reimbursement requests for the travel of external attendees.</td>
</tr>
</tbody>
</table>
Project Results and Visibility (WPH2)

Dissemination activities during and after the project

A dissemination and communication strategy was developed at the start of the project to actively promote the EUReMS project among the target groups: MS societies, existing MS registers/centres, potential data providers, MS scientific community and EU and national health authorities and policy decision-makers.

The main outcomes were the following:

- Development of a project logo, template for the project presentations and project website were developed, M02.
- First draft of the EUReMS brochure for dissemination and a banner for external meetings issued, M03.
- Poster presentation at the ECTRIMS Congress in Amsterdam, October 2011, M04.
- Lancet of Neurology (Editorial) on EUReMS published in October 2011, M04.
- Establishment of a list of stakeholders for communication purposes, with the first Consensus meeting, M04.
- Appointment of an external communication consultant in M17.
- Review and adaptation of the EUReMS project communication material with special attention to the upcoming Second Consensus meeting EUReMS meeting 2nd October 2013.
- Dissemination of public reports on EUReMS progress, M06, M16 and M 36 to the stakeholders and the SAB.
- Promotion of the project at external events dedicated EMSP stands with dissemination materials and updated information by EMSP at the following events: the MS Frontiers (2011 and 2013); the ECTRIMS congresses (2012, 2013 and 2014).
- Regular dissemination of information on the EUReMS to interested parties and relevant projects, such as the PARENT JA.
- A dissemination plan for the final stage of the project (M36-M39).
- Appointment of a PR Consultant in M38 to draft the Final publishable report on EUReMS.
- Dissemination of the Final publishable report and updated brochure to the stakeholders.
- Dissemination event held at the ECTRIMS/ACTRIMS Congress, 12th September 2014 in Boston, USA, attended by members of the SAB and stakeholders.
- Poster presentation on the first results from the EUReMS Studies at the ECTRIMS/ACTRIMS Congress 2014.

All documents concerning dissemination of EUReMS project results are appended in Section 12.

Key messages:

The project motto is “Better outcomes with better data”.

The EUReMS will be used to better understand and ultimately beat MS through more and better data. As a pioneer in this field, EUReMS has identified and pooled MS-related data from different registries – hospitals, MS societies and research centres across Europe –

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and has created a cross-border partnership for its safe and effective storage, analysis, interpretation and dissemination. EUReMS data enables analysis of:

- Costs and resources,
- Age and gender specific trends,
- Disease modifying drugs and their impact.

The project is closely aligned with the European Commission’s effort to fight health inequalities faced by European citizens. More and better data can drive policy improvements and provide incentives for new research.

The inclusion of the patients’ perspective adds significant value to the project.

**Project website**

The EUReMS Website is [www.eurems.eu](http://www.eurems.eu). The site is maintained by the EMSP and will be active for at least 2 years after the project.

**Publication, Abstracts, Articles**

**Peer Review Publications originating from the EUReMS project**

- K-M Myhr, MD, N Grytten Torkildsen, PhD, Survival in MS: Current Insights from International Registries and Databases, Supplement to the International Journal of MS Care, Sept. 2012, Vol. 14 Suppl. 4, p.5-10

**Scientific posters on EUReMS results**

- T Schyns-Liharska, M Pugliatti, P Flachenecker, D Pitschnau-Michel, J Hillert, T Friede and O Rienhoff, on behalf of the EUReMS Consortium: European Register For Multiple Sclerosis (EUReMS) – A tool to assess, compare and enhance the status of people with MS throughout the European Union, 2011
- P Flachenecker, K Buckow, M Pugliatti, for the EUReMS Consortium: Multiple sclerosis registries in Europe – results of a systematic survey, 2013
- P Flachenecker, K Buckow, D Ellenberger and J Hillert, for the EUReMS Consortium: Assessment of the patients’ perspective in the European Register for Multiple Sclerosis (EUReMS): Study protocol and first results of the PRO study, 2014
Evaluation of the project (WPH3)

As required in Annex I, an external evaluator was appointed. The independent expert was selected in M07 and worked with the EMSP management team throughout the whole project to collect the necessary data foreseen in the plan for evaluation. The external evaluator personally attended several project meetings and SC teleconferences. A final evaluation report on the EUReMS project was produced by the Advisor in M28 and appended together with the initial evaluation plan in Appendix 12.

Participant or partner feedback
Interviews with project associated and collaborating partners were undertaken by both the project external evaluator and the communication external consultant at the occasions of the project meetings and by telephone interviews. The results of the partner feedback surveys conducted by the external evaluator were summarised and presented to the SC and in the final Evaluation report. Partners’ feedback has been also widely used to prepare the final dissemination materials on the project, e.g. the Publishable report, the EUReMS brochure and website.

Process evaluation
The EMSP coordination team continuously monitored the progress of the project activities and updated and consulted the SC at the regular videoconferences and at the project meetings.
The indicators for process, output and outcome evaluation as set out in the Grant Agreement are listed in the Table 5.
<table>
<thead>
<tr>
<th>Process Indicators</th>
<th>Output Indicators</th>
<th>Achieved</th>
<th>Month</th>
<th>Outcome evaluation/ Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective 1</strong></td>
<td><strong>Define the vision and mission of the EUReMS</strong></td>
<td>18 Reponses received from SC, SAB and Stakeholders on the survey conducted by the Scientific Coordinator. Survey Template and Results in <a href="#">Appendix 13</a></td>
<td>M03</td>
<td>These allowed to establish the EUReMS Vision and Mission within the timeframe planned in the Annex</td>
</tr>
<tr>
<td>Dissemination of the Report</td>
<td>Nr of responses/ proposals to the report</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissemination of the Agenda of the First Consensus Meeting</td>
<td>Nr of participants at the First Consensus meeting</td>
<td>88 registered participants</td>
<td>M04</td>
<td></td>
</tr>
</tbody>
</table>
| **Objective 2**   | **Core data set for EUReMS** | - 18 MS Registries completed the WP2 Survey  
- 7 of the 18 Survey responders were also interviewed in order to obtain further details on these registries | M12   | 1. A number of MS registers identified as potential data providers to EUReMS (table 2);  
2. Core EUReMS data set that can be utilised to fulfil the EUReMS objectives, available. |
| Dissemination of the first draft of the report on currently functional MS databases in Europe | Nr of responses/ comments to the WP2 Leader |                                                                                             |       |                                  |
| **Objective 3**   | **Develop statistical methodology and data analysis strategies that will be applicable for studies utilizing the EUReMS** | - 4 working meetings (M15-M23)  
- 4 teleconferences (M14, M20, M22 and M24) | M24   | 1. List of Items for the test phase of EUReMS disseminated to the partners DPs  
D05.1- D5.4  
2. Submitted peer review publication on the test phase data methodology and analysis D04.1 |
<p>| Consultations with WP 1 and WP2 Working groups to define the template for data collection and analysis | Nr of teleconference and meeting with the WG WP1 and W2 |                                                                                             |       |                                  |
| <strong>Objective 4</strong>   | <strong>IT infrastructure for data collection, collaboration and information on MS across Europe that can be expanded for future research</strong> | Test data from 3 MS registries, Sweden, Spain and Germany | M33   | Drafted Import frameworks |
| Functional test of the IT working platform | Nr of tests performed on the IT platform by DPs partners |                                                                                             |       |                                  |
| Running test phase of the EUReMS IT platform | Nr of tests of the EUReMS export procedure for statistical analyses | 22 Import Frameworks for 11 MS registers participating in the EUReMS1 Studies DMD1, EPI1 &amp; PRO-1 (examples D08.3a, b &amp;c) | M36   | Collect productive data in the EUReMS database and perform data analysis according to the CSPs |</p>
<table>
<thead>
<tr>
<th><strong>Objective 5</strong></th>
<th><strong>Define the ethical principles, procedures and policies for establishing and operating EUReMS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal and external consultations on legal, regulatory, and ethical framework</td>
<td>Number of external advisors consulted and number of partners that have commented on the first draft</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Objective 6</strong></th>
<th><strong>Ensure a sustainable and a geographical representative Network of high quality data providers to the EUReMS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intense recruitment of DPs for the EUReMS</td>
<td>Nr of independent MS Centres contacted (n1),negotiated (n2) and contracted (n3) for EUReMS</td>
</tr>
</tbody>
</table>

**Table 5 Indicators for process, output and outcome evaluation of EUReMS project**
**Discussion in relation to project objectives**

The EUReMS has achieved all its objectives in accordance with the planned schedule:

- A European wide collaborative platform, the EUReMS database, for systematic collection, exchange and analysis of longitudinal data on Multiple Sclerosis (MS) in Europe is now established:
- The aims of the EUReMS, its Vision and Mission, has been defined, endorsed by the associated and collaborating partners and widely disseminated;
- A core data set for EUReMS, that can be extracted from the currently existing national and regional MS registers and can be utilised to set up new MS Registries, has been defined and published;
- Procedures and methodology for MS data integration have been established and validated in the EUReMS1 Studies during the Test phase;
- The IT infrastructure for MS data collection, collaboration and information on MS across Europe that can be expanded for future research and project is available at the UMG;
- Ethical and legal framework for cross-border MS data collection has been defined, validated and published;
- A highly collaborating, geographically representative Network of MS data provider in Europe has been established by EUReMS.

**Major results and key findings**

EUReMS project has clearly demonstrated that:

- There is a high number (n>20) of national and regional MS registries in Europe;
- There is a high heterogeneity among the established MS registries concerning their objectives, structure, nomenclature, organisation (e.g. hospital-based vs. population-based; paper format vs. electronic format; neurologist vs. patients), quality control mechanisms, governance and usage;
- The common areas that are covered by MS data collection:
  - Epidemiology
  - Healthcare
  - Long-term therapy research
  - Support to clinical trials
  - Health related Quality of Life from the patients’ perspective (less frequent)
  - Cost and cost-effectiveness of treatment (less frequent)
  - Quality management of healthcare (less frequent)
- Patient-reported outcomes are underrepresented in the current MS registries;
- Harmonised and standardised integration of data from existing MS registries is possible;
- Integration of high quality MS data from different sectors and various sources can be achieved.

**Target groups and added value**

EUReMS lays the foundation for systematic MS data collection and analysis. By doing so, the EUReMS project aligns with the Second Health Programme of the European Commission in terms of both priority areas and scope. The Health Programme objectives are to promote health, including the reduction of health inequalities, and to generate and disseminate health information and knowledge. The inclusion of the patients’ perspective adds significant value to the project.
Further use of the project results

The project is closely aligned with the European Commission’s efforts to fight health inequalities faced by the European citizens. More and better data can drive policy improvements and provide incentives for new research.

The first phase of the EUReMS under the current Health Programme is now complete. The information gathered through EUReMS is being managed by and stored at the Medical Centre of the University of Göttingen, Germany. Its dissemination is coordinated by EMSP, on the basis of access regulations developed within the EUReMS Scientific Board.

EMSP aims to build on the knowledge, experience and momentum achieved between 2011 and 2014 to encourage a growing number of MS registries across Europe to adopt EUReMS protocols of data pooling and analysis.

The aim for the post-2014 period is to use the newly created data infrastructure in collaboration with existing and emerging registries. This will eventually lead to a pan-European data pool to better assess the situation of people with MS.

To ensure the future development of the European MS register and secure additional support, the EUReMS Consortium has been working throughout the project duration in a broad collaboration with stakeholders and liaising with project partners over further studies. All EUReMS key stakeholders are committed to ensuring that the knowledge and momentum gained during the first three years of the project is sustained and that the project continues to grow and develop for the benefit of all concerned, and in particular, for the tens of thousands of people affected by MS in Europe and beyond.

Another important goal is to extend the project by considering the financing opportunities available under EU and industry programmes or frameworks.

Major lessons learned and recommendations:

One of the major strengths of the EUReMS project is that it gathers partners from different MS sectors such as MS Societies, public health organisations, research and academic organisations and from different cultural backgrounds, thus bringing their unique perspectives directly at the decision making level of the project. This has certainly enriched the EUReMS’ Missions and Objectives. At the same time, this has posed some challenges at the operational level of the project when translating the EUReMS’ Missions to concrete actions (M6-M14). At that stage of the project, it became evident that there is a need to hold frequent focussed meetings.

The planned project meetings were not sufficient to properly organise and advance the WP3 and WP4 work within the expected timelines. Therefore three additional working meetings were requested to the project officer and were held from M 14 till M30. Also, monthly Webex teleconferences were held to support and monitor the progress of WP3 and WP4. It is commonly agreed now that a series of focussed meetings for individual work packages during the early stage of the project would have been most effective for the initiation of the EUReMS studies.

There are several major international MS data register projects at varying stages of development and activity. During the last three years, EUReMS has made substantial progress in this field and can make a significant contribution to future developments,
with a particular emphasis on keeping patients-reported outcomes and patient-centered healthcare at the top of the agenda.

However, it is also clear that no single data register project can, or should try to, supplant existing projects.

The concept that would appear to have the best chance of success would be to establish a collaborative grouping of all stakeholders, led by a Joint Coordinating Centre which would serve the combined purpose of:
- bringing together and coordinating the contributing MS data register programmes;
- designing, formulating and leading a combined expression of interest/full proposal for funding
- managing and coordinating the combined (joint) programme in the event of a successful application
- maximising the pooled expertise, data and health intelligence housed in current and future European and international MS data registers.

EMSP is not equipped to coordinate the next stage of EUReMS alone, but is exploring the possibility of acting as an independent broker bringing together groups and individuals with interest in the pooling of MS patient data on a European or even global level.

The potential for competitiveness among existing registers suggests it may not always be easy to steer the project. However, it seems desirable to make a joint project application, for work led by committed and experienced people from the patient and scientific communities, helped by a wider Steering Committee of the MS players currently involved in EUReMS and other key stakeholders. This would allow future work to significantly improve the lives of those affected by MS, as well as contribute to the understanding that can help to create a world free of the condition.
Annexes

Deliverables:

D01.1: First year Interim report
D01.2: Second year Interim report
D02. Final publishable report on the Project
D03.1: EUReMS Consensus Statement
D04.1: Publication on currently functional MS databases: “Multiple sclerosis registries in Europe - results of a systematic survey”, in MS Journal, published by SAGE publications, April 2014
D04.2: EUReMS Core Data Set
D05 Summary of methodological approaches:
   D05.1: Clinical Study Protocol (CSP) for DMD1
   D05.2: CSP for EPI1-s
   D05.3: CSP for EPI1-d
   D05.4: CSP for PRO1
D06.1.a: Abstract DMD1 Study
D06.1.b: Presentation of DMD1 at ECTRIMS 2014
D06.2: Abstract for EPI1-s Study
D06.3a: Poster EPI1-d Study
D06.3.b: Presentation at ECTRIMS 2014
D06.4a: Poster PRO1 Study
D06.4.b: Presentation of PRO1 at ECTRIMS 2014
D07.1: EUReMS Collaboration Platform
D07.2: EUReMS collaboration Platform SOPs
D08.1: EUReMS IT Structure
D08.2: Screenshot of the export interface
D08.3: EUReMS instructions for data transfer
D08.3.a: EUReMS Import Framework, example DMD1
D08.3.b: EUReMS Import Framework, example EPI1
D08.3.c: EUReMS Import Framework, example PRO1
D09. EUReMS Charter
D10.1: EUReMS Agreement with data providers
D10.2: EUReMS data hosting contract

Appendix:

Appendix 1. Terms of References
Appendix 2. Agendas/Minutes of the Steering committees TC
Appendix 3. Kick off meeting, 3-4 July 2011, Luxembourg, Lx, Agenda; List of participants; Minutes
Appendix 4. First Consensus meeting, 19 October 2011, Amsterdam, NL, Agenda; List of participants; Minutes
Appendix 5. EUReMS project meeting, 21-22 May 2012, Barcelona, ES, Agenda; List of participants; Minutes
Appendix 6. WP Leaders working meeting, 13th September 2012, Frankfurt, DE, Agenda; List of participants; Minutes
Appendix 7. Workshop 10th October 2012, Lyon, FR, Agenda; List of participants
Appendix 8. Workshop, 31 January 2012, Frankfurt, DE, Agenda; List of participants; Minutes
Appendix 9. Workshop, 8 May 2013 London, UK, Agenda; List of participants; Minutes
Appendix 10. Second Consensus meeting, 2 October 2013, Copenhagen, DK, Agenda; List of participants; Minutes
Appendix 11. Final Project meeting, 10 June 2014, Brussels, BE, Agenda; List of participants; Minutes
Appendix 12. Evaluation report
Appendix 13. WP1 survey and results