Transfer of the Common Database and coordinating activities of SCPE to the JRC

SCPE: network of population-based registries for the epidemiological surveillance of cerebral palsy in Europe

2016
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SCPE: network of population-based registries for the epidemiological surveillance of cerebral palsy in Europe

Simona Martin, Agnieszka Kinsner-Ovaskainen, Javier de la Cruz, Monica Lanzoni, Ciarán Nicholl

2016
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– Part of the European Platform for Rare Diseases Registration

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Foreword

Cerebral Palsy (CP) is the commonest cause of severe physical disability in children in Europe. Its overall prevalence is just below 2 per 1000 live births. Prevalence of CP is a key public health indicator for child health and this needs to be monitored.

The network of population-based registries for the Surveillance of Cerebral Palsy in Europe (SCPE) is specialised in the epidemiologic surveillance of CP. Present in 23 countries – 20 EU Member States and three EFTA countries – and with a total of 31 member registries, the SCPE network is internationally recognised and valued for its longstanding active role in monitoring CP prevalence over time and across Europe, in harmonising clinical CP information through the development of a common language for describing children with CP and promoting comparability of data. Along with providing a medical educational tool for patients and healthcare providers, the SCPE’s contributions to the scientific literature are of high relevance in the clinical, research and public health fields.

Based on the importance and quality of these outputs, a sustainable solution for the continuation of the SCPE network’s work was ensured by the successful transfer of its European-level coordinating activities, including the central database, to the European Commission’s Joint Research Centre, a process completed in collaboration with the Directorate-General for Health and Food Safety (DG SANTE). This transfer to the European Commission closes a circle which was initiated in 1998, i.e. the birth of SCPE. Since then, the coordinating activities were funded in the frame of successive European Commission’s projects and programmes: from 1998 to 2000 by the Directorate-General Research, Science and Technology; from 2002 and 2004 by the Directorate-General Research and from 2005 to 2014 by the (then) Directorate-General Health and Consumers.

Today, the core SCPE activities are part of the European Platform on Rare Diseases Registration, a sustainable foundation which is independent of all national, private and commercial interests. Thus, the excellent work and dedication of those
who have made SCPE what it is today, with its remarkable scientific, public health and social dimensions, will be continued and further developed. This work contributes to providing equitable care and better quality of life for people with CP and emphasises the importance of the sustainability function of the Rare Diseases Platform.

Elke Anklam

*Director*

Joint Research Centre

Directorate F–Health, Consumers and Reference Materials
ABSTRACT

In the framework of implementing European Commission’s strategy in the field of rare diseases, the Directorate-General Joint Research Centre (JRC) and the Directorate-General for Health and Food Safety (DG SANTE) signed in December 2013 the Administrative Arrangement (AA) on the ‘Development and Maintenance of the European Platform on Rare Diseases Registration’. One objective of the AA was the transfer of the European-level coordination activities of SCPE to the JRC.

SCPE is a network of population-based registries for the surveillance of cerebral palsy (CP) active since 1998. Currently it has 31 members in 23 EU/EFTA countries, out of which 23 members are actively providing data to the JRC-SCPE Central Registry. SCPE promotes quality and harmonization of CP definition/description, develops collaborative epidemiological and clinical research about CP, disseminates knowledge for patients, health care professionals and key stakeholders, develops best practice in monitoring trends in CP and raises standards of equitable care for people with CP. All this improves outcomes for individuals with CP. Dissemination of this evidence-based information to policy makers is helpful to facilitate provision of appropriate, accessible, cost-effective care management programmes aimed to improve the quality of life for children and young people with CP and for their caregivers.

In order to offer a sustainable solution for the continuation of the SCPE activities, to secure the results of former work and to keep the network functioning, it was agreed that SCPE becomes part of the European Platform for Rare Diseases Registration being developed at the JRC, since the diseases/conditions it deals with belong to the category ‘rare’.

This report presents the preparation phase, the negotiations and the procedures carried out for the effective transfer of the SCPE coordinating activities, including the Common Database, to the JRC. The different types of activities and the involvement of different services (legal, IT, information security, and procurement) in a concerted action are detailed.
The establishment of the new JRC-SCPE Central Registry (CR) located at the JRC, Directorate F–Health, Consumers and Reference Materials, Unit F.1–Health in Society, corresponds to the ‘data repository’ function of the Rare Diseases Platform. The CR activities including collection of data from the registries, data management, communication with the registries, production of dissemination materials, and management of the website are described. In addition, the role and functioning of the new joint JRC-SCPE Management Committee and JRC’s role in supporting also other activities of the network (Annual Plenary meetings, SCPE Working Groups) are presented.

The accomplishment of the transfer is a milestone in the development of the European Platform on Rare Diseases Registration.

1. Former Public Health Policy Support Unit, Institute for Health and Consumer Protection (until 1 July 2016).
1. Introduction

European Commission’s strategy in the field of rare diseases, as expressed in the Commission Communication (COM (2008) 679 final) [1], focuses on three main areas: i) improving the recognition and visibility of rare diseases; ii) supporting policies on rare diseases in the Member States for a coherent overall strategy, and iii) developing cooperation, coordination and regulation for rare diseases at EU level. Alongside the Communication, the Council Recommendations (2009/C 151/02) [2] emphasise the need for sustainability in the field of rare diseases.

Implementing the EU policies in the field of rare diseases, the Directorate-General Joint Research Centre (JRC) and the Directorate-General for Health and Food Safety (DG SANTE) signed in December 2013 the Administrative Arrangement (AA) on the ‘Development and Maintenance of the European Platform on Rare Diseases Registration’ [3]. One of the main objectives of the AA is the transfer of the European-level coordination activities of SCPE to the JRC.

SCPE (Surveillance of Cerebral Palsy in Europe) is a network of population-based registries for the surveillance of cerebral palsy active since 1998. It has now 31 members in 23 EU/EFTA countries. SCPE promotes quality and harmonization of cerebral palsy (CP) definition/description [4][5][6][7], develops collaborative epidemiological and clinical research about CP, disseminates knowledge for patients, health care professionals and key stakeholders, develops best practice in monitoring trends in CP [8][9] and raises standards of equitable care for people with CP [10]. All this improves outcomes for individuals with CP. Dissemination of this evidence-based information to policy makers is helpful to facilitate provision of appropriate, accessible, cost-effective care management programmes aimed to improve the quality of life for children and young people with CP and for their caregivers.

The transfer of SCPE coordinating activities to the European Commission’s Joint Research Centre fulfilled in close collaboration with DG SANTE is aimed to ensure a sustainable solution for the continuation of SCPE activities, in order to
secure the results of former work and to keep the network functioning. The JRC-SCPE Central Registry becomes part of the European Platform on Rare Diseases Registration, since the diseases/conditions the network is dealing with belong to the category ‘rare’. This is in accordance with the general objective of the Platform to support and coordinate rare diseases registries and networks in view of their sustainability.

The European added value of the SCPE network comes from the pooling of data to monitor the prevalence of a series of neurodevelopmental conditions over time with a standard methodology. The SCPE is now an internationally established network that provides relevant scientific and public health information at European level.

The SCPE network has shown the advantages of a European-wide network to monitor rates of CP, particularly on subgroups of children such as those from multiple births, of very low birth weight or with deviant intra-uterine growth. Variations in prevalence and outcome of CP exist between and within countries of the EU. Understanding the nature of this variation is the first step to its reduction. While some variations are expected between countries, the ones which are due to differences in the provision of care and management strategies and to social economic differences are not considered acceptable.

SCPE’s previous efforts to harmonize the definition and classification of CP, including associated impairments and description of Magnetic Resonance Imaging, have evoked great interest in Europe and internationally (e.g. collaborative research with the Centre for Disease Prevention and Control (CDC) in US, and CP-Australia). This work should now be extended and the findings translated for use in all Member States, not just those with a CP registry.

EU states the need for evidence-based information to facilitate the provision of appropriate, accessible, cost-effective care management programmes for all those with CP. Inappropriate treatments consume scarce resources, and adversely impact on the quality of life of affected children and their families. Dissemination and use of this information by policy makers, health professionals, family and carers will improve the quality of life of children and young people with CP.
The transfer of SCPE coordinating activities to the JRC proved to be itself a complex process. This report gives an overview about the experiences of the Unit F:1–Health in Society, synthesised in the establishment of the new JRC-SCPE Central Registry and the new joint coordinating structure, the JRC-SCPE Management Committee. These were established by accomplishing a plethora of procedures with the involvement of different services: legal, IT, information security, data protection, intellectual property rights, and procurement. A close and very helpful collaboration between JRC and DG SANTE accompanied the whole process.

The finalisation of the transfer and the establishment of the new, fully operational structures are a milestone in the development to the European Platform for Rare Diseases Registration. It represents the basis for continuing the monitoring of cerebral palsy in Europe. The output of this activity is highly relevant for European public health and will be open to a wide range of stakeholders including healthcare providers, researchers, patients, pharmaceutical industry, and decision makers. The final goal is to provide strong benefit for patient’s healthcare and may require public health action.
2 Description of the SCPE network (state 2014): identification of the structures and activities to be transferred

SCPE is a network of population-based registries specialised in epidemiologic surveillance of cerebral palsies (CP). It is active since 1998 with 31 members in 23 EU/EFTA countries.

2.1 Mission of the network

The mission of the SCPE network is to learn more about the cerebral palsies from surveillance of trends in prevalence rates, severity, associated impairments and secondary disabilities.

By using population-based surveys and registries across Europe the SCPE network aims to:

• promote quality and harmonization of definition and description of CP;
• develop collaborative epidemiological and clinical research projects about CP, attracting young researchers to the field, in partnership with individuals with CP and their carers;
• disseminate knowledge about CP for individuals affected by CP, health care professionals and key stakeholders, including via academic publications;
• develop best practice in monitoring trends in CP;
• raise standards of equitable care for all people with CP through the life span and thus improve outcomes and quality of life for individuals with CP and their caregivers.

CP is an umbrella term referring to a group of conditions with different aetiologies, different birth prevalence, some of which are extremely rare and some of which continue to be elucidated.

CP is the commonest cause of severe physical disability in children in Europe. Its overall prevalence is just below 2 per 1000 live births. SCPE has demonstrated a reduction in prevalence in some birth weight and gestational age groups probably
related to an improvement in obstetrical and neonatal care. It is critical to continue to monitor this key public health indicator for child health.

Recent SCPE research projects included the exploration of variations in access to health care and outcome of care as a function of socio-economic indicators and the development of an international consensus on a classification for neuroimaging findings in CP. This is expected to be the basis for a new era in monitoring the different conditions and aetiologies considered under the umbrella term of CP. It will facilitate comparisons of rates, issuing clinical recommendations, international studies.

Collaboration with health economists has already started in order to assess the life-long formal and informal caring and support needs of children and youth with CP across Europe.

2.2. Funding

Since the start of SCPE, the coordinating activities were funded in the frame of successive European Commission’s projects and programmes under:

- DG Research, Science and Technology (1998-2000);
- DG Research (2002-2004);

The six EU grants included funding for core activities and for specific research projects. The core activities considered were the Common Database, activities of the Steering Committee, plenary meetings, website and dissemination activities.

The registry members of the SCPE network are individually funded at the regional or Member State level. Usually registries have several funding sources. Termination of funding at the individual registry level is the main reason why data submission to the network may be temporarily or permanently discontinued.

The funding scheme for the year 2014 was an Operating Grant awarded by DG SANCO/Chafea in the frame of the last Call of the Second EU Health Pro-
gramme. This grant covered the core functioning activities of the network until 31.12.2014.

2.3. Governance: SCPE coordination bodies/activities

The SCPE network of population-based registries is a public health and clinical research platform. The network’s governance structure that was in place before the transfer of SCPE coordinating activities to the JRC is described below.

Board of Members: The SCPE Board of Members consists of all Type (a) partners (all registry leaders). The Board of Members elects the members of the Steering Committee. Registry leaders and other registry staff meet annually in the SCPE Plenary Meeting.

Steering Committee: The SCPE Steering Committee (SC) coordinates the network activities and reports to SCPE Board of Members. The SC members elect the Chair of the SCPE Steering Committee who manages and coordinates the network. Since 2014, the Chair of the SCPE Steering Committee is Dr Catherine Arnaud from the Université Paul Sabatier in Toulouse, INSERM Epidemiology and Public Health, France.

Project coordination: In 2014 the project coordination (administrative part) was done at the Fundación Investigación Biomédica Hospital Universitario Hospital 12 de Octubre, Madrid, Spain (UM). Two persons were involved:

- Mr Abraham Pavon, Project Manager, providing support to all scientific and administrative network activities.
- Mr David Lora, Research Associate, responsible for statistics.

Working Groups (WG): The network runs its programme of activities through three Working Groups:

- Data WG: the WG includes clinical and epidemiological expertise. This WG plans the data submission campaign, assesses data quality, and proposes further harmonisation. The WG also provides critical input to SCPE Reference and
2. Description of the SCPE network

• Website and Dissemination WG: the main tasks of the Website and Dissemination WG are to develop dissemination contents and to increase visibility of website contents.
• Scientific activities WG: the WG promotes SCPE research activities and international collaborations.

SCPE committees and working groups organise regular meetings and call-conferences.

2.4. SCPE membership

The SCPE network is an unofficial voluntary non-profit organisation. A Memorandum of Understanding describes its functioning and establishes the categories of membership.

There are three types of members/partners:

Type (a) partners: European registries or surveys of children with CP fulfilling ALL of the following criteria:

• Registry type: population-based registries that cover a geographically defined area.
• Coverage: a minimum population of at least 3000 live births per year is required for membership, the ideal number of births should be between 10000 and 30000 live births per year.
• Ascertainment: registries use multiple sources of ascertainment.
• Age at registration: closest to five years old.
• Type of data: individual data and denominators.
• Core data: registries comply with the SCPE requirements in terms of data collection.
• Data standardisation: follow SCPE recommendation for inclusion and classification of cerebral palsy.
• Data quality: comply with the SCPE guidelines on quality assurance to ensure
reliability and accuracy of data both from its registry of children with CP and on denominator data.

- **Timeliness:** registries transmit the relevant data to the SCPE Common Database in a timely manner.
- **Ethical approval:** ensure compliance with the relevant local research ethics requirements.
- **Dissemination:** findings from SCPE work disseminate to their local, regional and national networks.

The SCPE partner is the registry and it is usually represented by the registry leader or his/her representative.

**Type (b) partners:** professionals with relevant skills and expertise in the neuro-developmental field:

- **Expertise:** bring expertise from relevant skill areas, such as neuro-imaging, epidemiology, public health, educational therapies, socio-economic analysis, that are required to achieve the aims of the SCPE network.
- **Research:** promote the use of SCPE Common Database in collaborative research studies external to SCPE.

**Type (c) partners:** European or international organisations or projects with interest in the work performed by SCPE. They are eligible if they can contribute to:

- **Collaboration:** help the SCPE network develop appropriate and valued areas of research such as inequalities in health, representativeness of registries in Europe, influence on stakeholders, impact on families.
- **Dissemination:** assist in the dissemination the SCPE network outputs.

Any person or organisation whose work focuses on improving understanding of or outcome from CP and/or other neuro-developmental impairment is eligible for membership. CP registries apply for membership, whereas professionals or organisations are nominated or invited to join. The list of Type (b) and (c) partners is being revised. Two Type (b) members seated in the Steering Committee in 2014.
When the network was founded in 1998, 14 registries from eight countries started providing individual data on CP cases and population denominators to the SCPE Common Database. In 2014, the network was present in 23 countries with 31 members, including 20 EU Member States (Austria, Belgium, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Portugal, Slovenia, Spain, Sweden, United Kingdom) and three EFTA Countries (Iceland, Norway, Switzerland) (see Table 1).

The complete list of SCPE members with the SCPE code, site, registry name, registry status (active or discontinued) and the registry coverage area are presented in Table 2 and Table 3.

Table 1. SCPE member registries by country (state November 2014).

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<tr>
<th>EU/EFTA Member States</th>
<th>Code and Registry Area</th>
<th>Count</th>
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<tr>
<td>Belgium</td>
<td>C27 Belgium</td>
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<tr>
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<td></td>
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<td>Germany</td>
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<td>12 Greece</td>
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<td>23 United Kingdom</td>
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<td>C11 Merseyside</td>
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Table 2. SCPE member registries: code, site, name and status (state November 2014).

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<th>Code</th>
<th>Site</th>
<th>Registry Name</th>
<th>Status</th>
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</thead>
<tbody>
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<td>Register for childhood disabilities and perinatal survey (RHEOP)</td>
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</tr>
<tr>
<td>C02</td>
<td>Toulouse (FR)</td>
<td>Childhood Disabilities Registry of the Haute-Garonne County</td>
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<td>C03</td>
<td>Edinburgh (UK)</td>
<td>Scotland CP Registry</td>
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<tr>
<td>C04</td>
<td>Cork (IE)</td>
<td>Cork and Kerry counties CPR</td>
<td>Active</td>
</tr>
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<td>Belfast (UK)</td>
<td>Northern Ireland Cerebral Palsy Register (NICPR)</td>
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<td>C06</td>
<td>Goteborg (SE)</td>
<td>CP Register of Western Sweden (CPWS)</td>
<td>Active</td>
</tr>
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<td>C07</td>
<td>Dublin (IE)</td>
<td>Eastern Area CP Study</td>
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<td>C08</td>
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<td>C09</td>
<td>Oxford (UK)</td>
<td>4 Child</td>
<td>Discontinued</td>
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<td>C10</td>
<td>Tubingen (DE)</td>
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<td>C11</td>
<td>Liverpool (UK)</td>
<td>Mersey Cerebral Palsy Register</td>
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<td>Copenhagen (DK)</td>
<td>National Cerebral Palsy Register (NCPR)</td>
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<td>Viterbo (IT)</td>
<td>Central Italy Cerebral Palsy Register</td>
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<td>C14</td>
<td>Arnhem (NL)</td>
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Table 2. (cont.)

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<th>Code</th>
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<th>Registry Name</th>
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<td>C21</td>
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<td>C24</td>
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<td>C28</td>
<td>Zagreb (HR)</td>
<td>Croatian Cerebral Palsy Register</td>
<td>Active</td>
</tr>
<tr>
<td>C29</td>
<td>St Gallen (CH)</td>
<td>CP register–St Gallen canton</td>
<td>Active</td>
</tr>
<tr>
<td>C30</td>
<td>Malta (MT)</td>
<td>CP Register project</td>
<td>Active</td>
</tr>
<tr>
<td>C31</td>
<td>Athens (GR)</td>
<td>CP Registry</td>
<td>Active</td>
</tr>
</tbody>
</table>

Table 3. SCPE active member registries coverage (state November 2014).

<table>
<thead>
<tr>
<th>Country</th>
<th>Code</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>C01</td>
<td>Isère &amp; Savoie (Grenoble–FR)</td>
</tr>
<tr>
<td></td>
<td>C02</td>
<td>Haute-Garonne (Toulouse–FR)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>C05</td>
<td>Northern Ireland (Belfast–UK)</td>
</tr>
<tr>
<td></td>
<td>C08</td>
<td>North of England (Newcastle–UK)</td>
</tr>
<tr>
<td>Sweden</td>
<td>C06</td>
<td>Western SW (Goteborg–SE)</td>
</tr>
<tr>
<td>Ireland</td>
<td>C07</td>
<td>Eastern area (Dublin–IE)</td>
</tr>
</tbody>
</table>
Table 3. (cont.)

<table>
<thead>
<tr>
<th>Country</th>
<th>Code</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>C10</td>
<td>South-West (Tubingen–DE)</td>
</tr>
<tr>
<td>Denmark</td>
<td>C12</td>
<td>National (Copenhagen–DK)</td>
</tr>
<tr>
<td>Italy</td>
<td>C13</td>
<td>Central (Viterbo–IT)</td>
</tr>
<tr>
<td>Norway</td>
<td>C15</td>
<td>National (Tonsberg–NO)</td>
</tr>
<tr>
<td>Spain</td>
<td>C18</td>
<td>Madrid area (Madrid–ES)</td>
</tr>
<tr>
<td>Slovenia</td>
<td>C19</td>
<td>National (Ljubljana–SI)</td>
</tr>
<tr>
<td>Portugal</td>
<td>C21</td>
<td>National (Lisbon–PT)</td>
</tr>
<tr>
<td>Latvia</td>
<td>C22</td>
<td>Riga area (Riga–LV)</td>
</tr>
<tr>
<td>Hungary</td>
<td>C23</td>
<td>Pecs area (Pecs–HU)</td>
</tr>
<tr>
<td>Iceland</td>
<td>C25</td>
<td>National (Greningar–IS)</td>
</tr>
<tr>
<td>Austria</td>
<td>C26</td>
<td>Tyrol (Innsbruck–AT)</td>
</tr>
<tr>
<td>Belgium</td>
<td>C27</td>
<td>National (Leuven–BE)</td>
</tr>
<tr>
<td>Croatia</td>
<td>C28</td>
<td>Zagreb area (Zagreb–HR)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>C29</td>
<td>Eastern area (St Gallen–CH)</td>
</tr>
<tr>
<td>Malta</td>
<td>C30</td>
<td>National (La Valetta–MT)</td>
</tr>
<tr>
<td>Greece</td>
<td>C31</td>
<td>Athens area (Athens–GR)</td>
</tr>
</tbody>
</table>

Non-active SCPE registries in 2014 were C01 (UK), C04 (IE), C09 (UK), C11 (UK), C14 (NL), C16 (IT), C17 (IE), C20 (LT), C24 (CY).

2.5. SCPE IT infrastructure

The SCPE IT infrastructure includes the following elements that were developed, maintained and updated in the framework of EU grants at the request of the SCPE network:
1. SCPE data submission web portal.
2. SCPE Common Database.
3. SCPE website.

2.5.1. SCPE data submission web portal

The SCPE data submission web portal was designed by the SCPE Common Database Centre with the aims to secure data transmission and to streamline the Common Database processes to obtain high quality data for surveillance. The web portal allowed registries to transmit and check their data files online.

Protected access was provided to SCPE members by the Grenoble team leader. The portal was used during the annual submission campaigns by more than 20 member registries.

The portal provides two important tools to registries: a stringent data check interface and a secure data upload system. The Data Checks application allows the management of case files and denominator files. When entering the Member Registry code, a customised notice informs on the data expected to be submitted on that year:

• Case management:
  – download all necessary documentation for data coding and transmission (guidelines, templates);
  – access feedback report from previous year data submission;
  – upload a text file with cases to submit;
  – read and print the warnings and errors detected by the system;
  – repeat previous steps after correction of the original file.
• Denominator management:
  – download previous year denominator file;
  – no data check for integrity of denominators are available.

For data submission, SCPE Common Database and Registry members used an application (the SCPE Data submission website) which was developed and hosted by an external company Ergole Informatique (Grenoble, France).
The site allowed data for customised submission (upload by local registries and download by Common Database Centre) and data checks with display of errors and warnings. After going through warning and error reports, case files were validated and eventually submitted. The upload and submission of Denominator files included integrity checks. The level of access to the portal of the SCPE Common Database allowed to follow the tasks performed by registries and to download validated files.

The SCPE data submission web portal was developed until 2009, when the coordination of the network was located at University of Grenoble. All IP rights were on University of Grenoble. The software was developed and maintained by Ergole Informatique. The application was developed in PHP language and uses a MySQL database for managing names and passwords, temporary uploaded data, and warning and errors detected. In addition, Ergole proprietary software (SPHYNX) was also used in order to customise queries to registries.

2.5.2. SCPE Common Database

The Common Database is the collection of anonymised data submitted by Registry members, checked and modified at the Common Database Centre. In 2014 the Database included 17000 CP cases and denominator data. Data provided since the start of the network covered the live-birth period 1976-2005. Most registries provide data annually. Some provide data at longer intervals. A few registries started submitting recently and their data were not yet included in the Common Database in 2014.

All data in the SCPE Common Database that comply with quality requirements are used in the statistical analysis for the surveillance of CP trends. This includes data from registries which discontinued their activity.

The activities of the Common Database Centre include: the annual campaign of data submission, data quality checks, personalised feedback to registries together with quality indicators, provision of guidelines for data submission, data use and data analysis. A large extent of database processes is not automatized and is still performed by the data manager with MS Access, MS Excel and STATA software.
The SCPE Common Database was hosted and managed by SCPE Co1 partner at Université Joseph Fourier, Grenoble, France, where the coordination of the network was based from 1998 to 2009. From 2009 to 2014, the coordination of the network was at Fundación Investigación Biomédica Hospital Universitario Hospital 12 de Octubre, Madrid, Spain.

In 2014 the members of the Common Database Centre and their tasks were:

**Dr Christine Cans**  
Medical Information Cluster, Head  
Senior Researcher–Epidemiology  
SCPE Coordinator 1998-2009  
SCPE Common Database Work Package Leader (until 2013)  
*Main tasks:* Coordination of SCPE Grenoble Common Database Centre.

**Dr Elodie Sellier**  
Medical Information Officer  
Senior Researcher–Epidemiology  
SCPE Common Database Work Package Leader (from 2014)  
*Main tasks:* Responsible for the data campaign from data call to production of preliminary prevalence results. – Coordination of Data working group, including coding and classification. – Data quality and control. – Feedback to registries on data submission. – Epidemiology advisor for publications on surveillance.

**Ms Catherine Tronc**  
Research Associate–Statistics  
SCPE Database manager  
*Main tasks:* Data management: download of data files, data checking and editing  
– Contact with registries for data-related issues.

**Ergole Informatique**  
The company based in the Grenoble area has been providing IT services to SCPE Common Database Centre since its start in 1998. Its main product is the software for data survey processing SPHYNX SCPE.  
*Main tasks:* Support and development for the data submission site.
2.5.3. SCPE website

The SCPE website (www.scpenetwork.eu) was owned by Fundación Investigación Biomédica Hospital Universitario Hospital 12 de Octubre, Madrid, Spain (UM). SCPE website was developed and is hosted and maintained by Innovatif, an IT company in Slovenia.

Two levels of access were established—public and private. The public part is multilingual (EN, DE, PT, LV, SE in test phase; FR, IT, ES in preparation) and it has two sections: the General information and the Reference and Training Manual (RTM). The access to the RTM (which includes a Training Manual with video sequences) requires registration and is granted on a case-by-case basis. The private part, only accessible to SCPE members, was used for archiving and communication purposes (exchange of documents, forum, etc.).

The website was developed as an open-access platform with Silverstripe Content Management System. It was managed by the SCPE Dissemination Working Group with technical support from the Madrid SCPE Registry member.

2.6. Conclusions on the structures and activities to be transferred

With respect to the coordinating activities it was concluded that:

- the Steering Committee will be adapted to the new situation
- JRC will support the activities of the Steering Committee, of other committees and of Working Groups when needed.

The structures identified for the transfer to the JRC were:

- the SCPE Common Database
- the SCPE data submission web portal
- the SCPE website.

As a result, the negotiation was applied to the above mentioned structures and activities.
3. Negotiation phase in view of the transfer

The negotiations between JRC and SCPE focused on two separate issues: the support of SCPE coordinating activities and the transfer of SCPE Common Database and software, including the website.

The negotiations took place on the occasion of meetings between the JRC and the SCPE Steering Committee, and during the 2014 Annual Plenary Meeting with all the registry leaders.

1. Meetings between JRC and the SCPE Steering Committee:
   • Amsterdam, 4 November 2013
   • Ispra, 23 May 2014
   • Tuebingen, 28 June 2014
   • Ispra, 18 September 2014
   • Norwich, November 2014

2. Meetings between JRC and the SCPE registries’ leaders:
   • Annual Plenary Meeting, Norwich, November 2014.

The terms of the transfer and the future functioning of SCPE were agreed between JRC and the SCPE Steering Committee during the meetings listed above and by e-mail exchange also used to provide documents of the network.

A roadmap for the transfer was proposed by JRC to the SCPE Steering Committee in June 2014 (see Figure 1).

The main points of the JRC proposal included: 1) Governance; 2) Transfer of the SCPE Common Database and SCPE website to the JRC; 3) Meetings; 4) Dissemination; 5) Activities offered by JRC to SCPE member registries; 6) Activities offered by JRC for adding value to the SCPE data.
3. Negotiation phase in view of the transfer

Figure 1. Main building blocks for the SCPE transfer. The objective is to provide sustainability to the SCPE network, by transferring the SCPE European level coordinating activities to the JRC.

**Governance**

The JRC-SCPE Management Committee will comprise selected SCPE representatives (SCPE Steering Committee) and JRC representatives. The JRC will organise the Management Committee meetings and call conferences.

**Transfer of the SCPE Common Database and SCPE website to the JRC**

- Legal framework: the JRC together with the organisations that host the SCPE Common Database and the SCPE website, and with SCPE member registries will establish a contract (collaboration agreement) that will lead to the transfer of SCPE Common Database and SCPE website to the JRC. Ownership of individual data will remain to the registries.
- Staff: JRC will ensure appropriate staff to effectively run the SCPE database and website at the Unit F.1 – Health in Society. Practical training of JRC staff at SCPE Common Database Centre in Grenoble will be organised.
Meetings

- SCPE meetings: JRC will organise and support the SCPE Annual Plenary meeting with participation of registry leaders. The meetings of the three SCPE working groups (Data WG, Website and Dissemination WG, Scientific activities WG) will also be organised and supported by the JRC.
- Scientific activities: JRC will support SCPE scientific activities such as international collaborations and organisation of scientific meetings with participation of SCPE partners.

Dissemination

- SCPE website: the SCPE website will be transferred to and hosted at the JRC. The content will be managed by JRC staff supported by the Website and Dissemination WG. The scientific content will be under the responsibility of the joint JRC-SCPE Steering Committee.
- Dissemination materials: JRC will produce dissemination materials such as leaflets, newsletters and factsheets, in close collaboration with the SCPE committees and working groups.

Activities offered by JRC to SCPE member registries

- Training workshops.
- Technical support for establishing new registries.

Activities offered by JRC for adding value to the SCPE data

- Dissemination of results to policy makers for decisions on health care, education, social services.
- Integration of SCPE data into larger information systems.

Further discussions with representatives of the SCPE Steering Committee and e-mail exchanges contributed to fine tune the list of activities, the mechanisms of collaboration and the legal requirements. An updated roadmap was presented by JRC to the SCPE members participating to the Annual Plenary Meeting in November 2014.

30 | Transfer of the common database and coordinating activities of SCPE to the JRC
At the 2014 Annual Plenary Meeting, the SCPE Board of Members approved an amended SCPE Memorandum of Understanding (MoU) that included transfer-related issues. In this MoU, the transfer to the JRC was presented as a way ‘to secure a sustainable solution for the continuation the SCPE activities’.

An amended governance structure described in the revised SCPE Memorandum of Understanding includes the JRC in the decision making process of the network (Figure 2). The new governance scheme includes JRC representatives in the JRC-SCPE Management Committee that comprise of SCPE elected members and JRC representatives. The JRC will organise the Management Committee meetings and call-conferences. JRC representatives will also participate in the Working Groups dealing with Data and with Website and Dissemination.

![Revised SCPE governance structure that includes the JRC in the decision making process of the network.](image)

**Figure 2.** Revised SCPE governance structure that includes the JRC in the decision making process of the network.
4. Preparation phase for the transfer

4.1. Legal considerations

After having identified the structures and activities to be transferred, the legal and administrative frame for the transfer needed to be established. In order to proceed with this, the Rare Diseases Group (Unit F.1–Health in Society) started an intensive collaboration with the JRC Legal Advice Unit and the Intellectual Property Rights (IPR) Office. This resulted as a first step in the necessity to clarify the ownership of the different structures to be transferred. Ownership and rights had to be defined for the following levels: the database infrastructure, the content and the particular data, the software and the website.

It has been identified that:

• University of Grenoble is the owner of the SCPE Common Database.
• SCPE registries are the owners of their individual data.
• Host of the SCPE website is Innovatif, IT Company in Slovenia.

These clarifications required an extensive exchange between the JRC (Unit F.1–Health in Society and Legal Affairs Unit A4) and the University of Grenoble (IP Office).

The legal frame for the transfer of SCPE coordinating activities to the JRC is the Collaboration Agreement. SCPE registries agreed to mandate University of Grenoble (IP Office) to negotiate the Collaboration Agreement for the transfer of their data to the JRC under the supervision of the SCPE Steering Committee.

The Chair of the SCPE Steering Committee was appointed to collect from all Registry Leaders or Legal Representatives the mandate for University of Grenoble to negotiate the transfer of the SCPE Common Database and the data submission web portal. These documents were provided to JRC when all signatures were gathered. In the meantime, the JRC Legal Advice Unit was in contact with University of Grenoble for preparatory steps.
4.2. Preparatory work for the transfer of the IT infrastructure

A meeting between a JRC staff member and the staff of the SCPE Central Database Centre in Grenoble took place in December 2014. The meeting covered the following topics of related to data submission and data management:

- Data submission.
- Quality checks.
- Validation of data.
- Feed-back report to registries.
- Derived items, modification of the database.
- Data requests.
- Data use.

These topics are covered in two series of documents, the SCPE Guide and SCPE Operating Procedures. It was agreed that these documents should be updated for the handover to the JRC.

The results of the meeting at the SCPE Database Coordinating Centre in Grenoble and of the discussions about the way to proceed are summarised in Table 4.

The technical characteristics of the SCPE IT infrastructure and the IT needs for its implementation at the JRC were discussed in detail between Unit F.1–Health in Society’s IT Support Group and the SCPE Common Database Centre.

The SCPE data submission web portal was developed and hosted by Ergole. The portal allowed data for customised submission and data checks with display of errors and warnings.

After going through warning and error reports, case files can be validated and eventually submitted. The upload and submission of Denominator files does include integrity checks.

The level of access to the portal of the SCPE Common Database allowed to follow the tasks performed by registries and to download validated files.
Table 4. *Summary of topics discussed with SCPE Database Coordinating Centre in Grenoble in December 2014.*

<table>
<thead>
<tr>
<th>Topics</th>
<th>Discussion</th>
<th>Next step/action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Documents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Guidelines and SOPs (Standard Operating Procedures)</td>
<td>There should be a unique document for all the guidelines (dedicated to the registries), and another document for all the procedures (dedicated to who manages the database).</td>
<td>All the SOPs should be ready as soon as possible, not later than mid-March 2015. SOPs have to be validated: some by the Data WG, others by the Scientific WG, all by the SC. The list of SOPs was circulated to SC, and was delivered to JRC (see Table 5).</td>
</tr>
<tr>
<td>– Others (e.g. list of registries)</td>
<td>List of registries (Index card summary) is available on the website.</td>
<td></td>
</tr>
<tr>
<td>– SOP on written feedback to registries</td>
<td>There was discussion about the level of details required for these SOPs.</td>
<td>A training session can be organised according to problems detected in the feedback. This is related, for instance, to subjects that appear to be important to guarantee the quality of data.</td>
</tr>
<tr>
<td><strong>Rules of functioning (rF)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The relationship between JRC and the SCPE Working Groups, Management Committee and SCPE Board should be described within the SOPs and listed in a specific document.</td>
<td>Need to identify within the SOPs in which parts of the work the database manager should ask an advice of JRC referent or of SCPE (Data WG or MC).</td>
</tr>
<tr>
<td></td>
<td>The database manager should be able to refer to a referent person (epidemiologist most of time) any time she needs to. Identification of the expert role of an SCPE epidemiologist who can give advice on history of the SCPE network, and on quality insurance of the data.</td>
<td>There is a need to identify the role of expertise of the SCPE senior expert (epidemiologist) and of the JRC referent (epidemiologist as well).</td>
</tr>
</tbody>
</table>
### Table 4. (cont.)

<table>
<thead>
<tr>
<th>Topics</th>
<th>Discussion</th>
<th>Next step/action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCPE website</strong></td>
<td>Data submission is performed currently through the old SCPE website. It would be easier if this was transferred to the new SCPE website.</td>
<td>Transfer of the link could be easily and quickly done. Transfer of the content of the old website will require more time.</td>
</tr>
<tr>
<td><strong>Improvements and/or developments</strong></td>
<td>Automatic constraints can save time, more can be implemented within the data submission software. Denominator data submission could be done in a different way, seeking for greater efficiency. Interest of training session for new registries was discussed.</td>
<td>Proposal can be made for new automatic constraints and improved denominator data submission.</td>
</tr>
<tr>
<td><strong>Manpower 2015</strong></td>
<td>The Operating Grant ends very soon (end of 2014). Working time has been asked by SCPE to JRC for the SCPE database manager during year 2015 for data transfer (finalizing procedures, 2015 data submission, training of the JRC database manager). Expertise working time has been discussed as well, that can be shared between experts from the SCPE WGs, and JRC professionals. Expertise working time include senior epidemiologist, senior clinician, and database manager.</td>
<td>Proposal of a collaborative work in 2015 between the SCPE Common Database Centre in Grenoble and JRC will be prepared by SCPE.</td>
</tr>
<tr>
<td><strong>Quality issues for the future submission</strong></td>
<td>Training might be completed by a pilot exercise of data submission within a subgroup of ‘voluntary’ registries (if not all registries). This exercise should be performed by JRC before their first ‘own’ data submission campaign (2015 or 2016).</td>
<td>SCPE has to propose quality indicators resulting from this pilot exercise. This list of quality indicators should be revised annually during the SCPE plenary meeting, on proposal of the Data WG.</td>
</tr>
</tbody>
</table>
### Table 4. (cont.)

<table>
<thead>
<tr>
<th>Topics</th>
<th>Discussion</th>
<th>Next step/action</th>
</tr>
</thead>
</table>
| Calendar of the data submission campaign    | The calendar of the 2015 data submission was discussed. It is described in SOP No. 1.  
Briefly; Spring–data submission period, Autumn–plenary meeting.          | 2015 calendar could be considered as a ‘model’ (template) of calendar for the next years. A face to face meeting of the Data WG (focused on the data submission) should be planned before summer time. |
| Miscellaneous                               | Identify key points of public health interest when monitoring CP (such as trends of prevalence, in severity, differences in care, etc.).  
Computer engineer could start working in January 2015 at JRC.  
Database manager could start working in March 2015 at JRC.               | SCPE (Website & dissemination WG) should collaborate with JRC on this.           |

### Table 5. List of SCPE network Guidelines (G) and Standard Operating Procedures (SOP) as reported by SCPE Database Coordinator on 10th December 2014. The necessary changes to be done before transferring the documents to JRC are summarise in the last column of the table.

<table>
<thead>
<tr>
<th>Document number</th>
<th>Title of the document</th>
<th>Version/date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>Guideline for data submission</td>
<td>4.3/04/2014</td>
<td>Add content with pages</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Update website location of some documents</td>
</tr>
<tr>
<td>G2</td>
<td>Guideline for data submission for denominators</td>
<td>4.2/03/2014</td>
<td></td>
</tr>
<tr>
<td>G3</td>
<td>Guideline for Congenital anomalies</td>
<td>2005/06</td>
<td>Need to be updated</td>
</tr>
<tr>
<td>G4</td>
<td>Guideline for syndromes</td>
<td>2007</td>
<td>Need to be updated (at least with the 2014 paper from Hayley)</td>
</tr>
<tr>
<td>G5</td>
<td>ICD 10 Q chapter in en.</td>
<td>2005</td>
<td></td>
</tr>
<tr>
<td>SOP1</td>
<td>Data submission campaign</td>
<td></td>
<td>Contains information about it, starting, during, ending</td>
</tr>
</tbody>
</table>
### Table 5. (cont.)

<table>
<thead>
<tr>
<th>Document number</th>
<th>Title of the document</th>
<th>Version/date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP2</td>
<td>Quality checks controls</td>
<td></td>
<td>During and just after the data software submission (feedback, data use excluded, for these see SOP7)</td>
</tr>
<tr>
<td>SOP3</td>
<td>Validation of the data + SCPE database (Access, Stata)</td>
<td></td>
<td>Including storage of the data (each registry and overall) and return of data to each registry – List of corrections made in Stata</td>
</tr>
<tr>
<td>SOP4</td>
<td>Software for data submission</td>
<td></td>
<td>Link in this SOP exists for giving access to SOP5</td>
</tr>
<tr>
<td>SOP5</td>
<td>Computerized constraints</td>
<td></td>
<td>Password required, to be asked to Ergole</td>
</tr>
<tr>
<td>SOP6</td>
<td>Feed back to the registries and network</td>
<td></td>
<td>Including safe storage of the different feedbacks year by year and per registry (global information, information per registry)</td>
</tr>
<tr>
<td>SOP7</td>
<td>Modifying the database</td>
<td></td>
<td>Contains – Adding information on already existing cases – Adding new cases for a birth year cohort (conditions) – Management when correcting errors</td>
</tr>
<tr>
<td>SOP8</td>
<td>Derived items of the SCPE Common Database</td>
<td></td>
<td>Comprises ‘derived’ items construction/decision, ‘b’ variable construction, Items for IUGR (Z score) calculation</td>
</tr>
<tr>
<td>SOP9</td>
<td>Guideline for data use</td>
<td></td>
<td>Need to be updated</td>
</tr>
<tr>
<td>SOP10</td>
<td>Guideline for asking data</td>
<td></td>
<td>Need to be updated</td>
</tr>
<tr>
<td>SOP11</td>
<td>Guideline for authorship</td>
<td></td>
<td>Need to be updated</td>
</tr>
</tbody>
</table>

The application was developed in PHP language and uses a MySQL database for managing names and passwords, temporary uploaded data, and warning and errors detected. In addition, Ergole proprietary software (SPHYNX) was also used in order to customise queries to registries. The developers recommended re-writing the programme as they considered the IT was out of date and would not stand...
to be transferred to and hosted on another website. A document from Ergole describing the application was made available to JRC. The Ergole document provided guidance on how to re-program the application. Ergole and the SCPE network provided the source code and all necessary files with ‘constraints and integrity rules’ at the request of JRC. An SOP for the transfer with access to the source code was also provided. The details of the new SCPE data submission web portal developed at JRC are presented in Section 6.

In 2015 the SCPE data submission portal worked properly but it required maintenance during the data submission campaign. It was agreed that it would be maintained until the end of 2015 data submission campaign.

Regarding the SCPE website JRC discussed with SCPE the plans for migrating the contents of the two SCPE websites, routine content management and controlling access to the different parts of the website. SCPE agreed to update contents in the public and private part, and to keep hosting the website at Innovatif until June 2015. Ultimately, the website should be transferred and managed by the JRC.

4.3. Meetings planned in 2015

A calendar of the meetings in 2015 was established. It was agreed that JRC would organise:

• Annual Plenary Meeting – planned for October/November 2015.
• Workshop Data Working Group – during the Plenary.
• Workshop Website and Dissemination Working Group – during the Plenary.
• Meetings of the Steering Committee/joint JRC/SCPE Steering Committee (three meetings).
• Workshop Scientific Activities Working Group, June 2015.
• Workshop Scientific Activities Working Group – collaboration with Australian network, project congenital anomalies and CP.

All meetings would take place at the JRC’s site in Ispra, Italy.
5. **JRC-SCPE Collaboration Agreement**

The JRC and the SCPE Network decided to establish a legal framework for the transfer and continuation of SCPE European level coordinating activities to the JRC.

At the SCPE 2014 Plenary Meeting, SCPE Registries updated SCPE Memorandum of Understanding in view of the transfer to the JRC. The Registries agreed to mandate the University of Grenoble (UG, Université Joseph Fourier) to negotiate a collaboration agreement with the JRC on behalf of all the Registries.

Following extended discussions between UG and SCPE coordination, UG sent the first draft to the JRC in February 2015. The JRC Legal Advice Unit had several exchanges with UG and a final draft was presented at SCPE plenary meeting in November 2015, approved by SCPE Steering Committee and sent to all Registries for signature in December 2015. The Collaboration Agreement entered into effect in January 2016 when signed by at least six member Registries.

On December 2016, 20 out of 23 active Registries signed the collaboration agreement. The signature is not expected from seven non-active Registries (see Table 6).

**5.1. Objectives of the Collaboration Agreement**

The collaboration takes place in the frame of the EU Platform on Rare Diseases Registration being developed at the JRC in agreement and close collaboration with DG SANTE.

Specific objectives of the agreement are:

- To enable the transfer of the SCPE Central Database, to secure a sustainable solution for the continuation of SCPE activities and to secure the results of the previous work.
• To establish the rules of transfer of intellectual property and determine the general terms and conditions for exploiting the results of this collaboration.

5.2. Responsibilities and roles of the parties

5.2.1. Responsibilities of the JRC

Following the entry into force of the Collaboration Agreement, the JRC becomes the JRC-SCPE Central Registry. The role of this Central Registry is to:

1. maintain and further develop a Central Database with data from registered children with cerebral palsy according to established coding methodologies,
2. coordinate and operate data collected from the Registries,
3. ensure data security/safety including the process of data transmission,
4. manage and analyse the data including data checking, standardisation, quality assessment, validation, statistical analysis and monitoring for further reporting and dissemination,
5. manage the SCPE website administration, maintenance, updates and development,
6. communicate with the Registries and give feedback on data-related issues and results of the monitoring,
7. analyse the data for monitoring reporting and give feedback on results of the monitoring,
8. evaluate requests for data use,
9. establish and maintain relations with other organisations within the remit of its role.

In addition, the JRC

(a) participates in and supports the coordinating activities of SCPE,
(b) organises meetings of the JRC-SCPE Management Committee and of the SCPE working groups,
(c) organises the SCPE Annual Plenary Meeting,
(d) organises scientific meetings and workshops,
(e) offers support for dissemination activities: newsletters, leaflets,
(f) offers support to the individual registries—e.g. IT support, etc.,
(g) supports the organisation of trainings,
(h) ensures to give visibility to the Registries,
(i) disseminates the output of data analysis in agreement with the management Committee,
(j) supports actions aimed at adding value to the SCPE data by: integration into larger health information systems, links to other databases (e.g. environmental data), dissemination of public health indicators to policy makers for decisions on primary/secondary prevention,
(k) promotes the registration of cerebral palsy across Europe.

5.2.2. Responsibilities and roles of the Registries

The role of the SCPE Registries is to:

1. transmit data to the JRC-SCPE Central Registry according to the annual calendar for data transmission (deadlines: February and October). The Registries remain the owners of their data and the JRC is granted rights of use on the data for the purposes of the activities set out in this Agreement,
2. provide feedback on the data processed at the JRC-SCPE Central Registry and on the output of data analysis; collaborate with the JRC-SCPE Central Registry for data validation,
3. contribute to the analysis and interpretation of the monitoring results and reports related to the data they provided,
4. inform the local/regional/national health authorities on the issues of concern from the results of the monitoring,
5. obtain and maintain ethical approvals if required by the applicable law at their site,
6. warn the JRC-SCPE Central Registry immediately of any difficulty which may prevent the SCPE Central Database from functioning.

5.2.3. Coordination

The JRC-SCPE Management Committee (MC) consisting of six representatives of the SCPE Network and two representatives from the JRC co-ordinates SCPE activities as follows:
(a) prepares and takes decisions on the JRC-SCPE activities under the Collaboration Agreement,
(b) decides on membership issues including applications for membership,
(c) facilitates the discussions between the Registries and the JRC-SCPE Central Registry concerning the execution of the activities under the Collaboration Agreement,
(d) supervises and supports the organisation of the annual SCPE plenary meeting,
(e) decides on applications for additional meetings and workshops,
(f) supervises and supports the activities of working groups,
(g) decides on applications for studies regarding protocol, data and authorship,
(h) gives permission to use any data from the SCPE central database,
(i) establishes and maintains relations with other organisations,
(j) promotes dissemination of work on cerebral palsy across Europe,
(k) facilitates the development of research projects,
(l) establishes policies and adopts documents related to the Management Committee and the JRC-SCPE Central Registry,
(m) develops quality assurance processes and guidelines to maintain and further improve data quality,
(n) decides on which data may be deleted from the SCPE central database, following request of a registry.

Decisions of the JRC-SCPE Management Committee are taken by consensus.

5.2.4. Responsibilities in the transfer of the SCPE Central Database

University of Grenoble and the Registries grant to the JRC a non-exclusive and royalty-free licence to use, re-use, modify, distribute copies, communicate to the public, and store the SCPE Central Database. These rights are intended to cover the entire content of the SCPE Central Database as delivered to the JRC following the signature of the agreement, as well as any future contribution to the SCPE Central Database made by the parties.
Table 6. Status of the signatures of JRC-SCPE Collaboration Agreement, as of December 2016. Note that only 23 active SCPE members, which are expected to sign the collaboration agreement, are listed in the table. The remaining seven non-active members are not foreseen to sign.

<table>
<thead>
<tr>
<th>SCPE Registries</th>
<th>Signed JRC-SCPE Collaboration Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>Site</td>
</tr>
<tr>
<td>C01</td>
<td>Grenoble, France</td>
</tr>
<tr>
<td>C02</td>
<td>Toulouse, France</td>
</tr>
<tr>
<td>C04</td>
<td>Cork, Ireland</td>
</tr>
<tr>
<td>C05</td>
<td>Belfast, United Kingdom</td>
</tr>
<tr>
<td>C06</td>
<td>Goteborg, Sweden</td>
</tr>
<tr>
<td>C07</td>
<td>Dublin, Ireland</td>
</tr>
<tr>
<td>C10</td>
<td>Tubingen, Germany</td>
</tr>
<tr>
<td>C11</td>
<td>Liverpool, United Kingdom</td>
</tr>
<tr>
<td>C12</td>
<td>Copenhagen, Denmark</td>
</tr>
<tr>
<td>C13</td>
<td>Viterbo, Italy</td>
</tr>
<tr>
<td>C15</td>
<td>Tonsberg, Norway</td>
</tr>
<tr>
<td>C18</td>
<td>Madrid, Spain</td>
</tr>
<tr>
<td>C19</td>
<td>Ljubljana, Slovenia</td>
</tr>
<tr>
<td>C21</td>
<td>Lisbon, Portugal</td>
</tr>
<tr>
<td>C22</td>
<td>Riga, Latvia</td>
</tr>
<tr>
<td>C23</td>
<td>Pecs, Hungary</td>
</tr>
<tr>
<td>C25</td>
<td>Reykjavik, Iceland</td>
</tr>
<tr>
<td>C26</td>
<td>Innsbruck, Austria</td>
</tr>
<tr>
<td>C27</td>
<td>Leuven, Belgium</td>
</tr>
<tr>
<td>C28</td>
<td>Zagreb, Croatia</td>
</tr>
</tbody>
</table>
Table 6. (cont.)

<table>
<thead>
<tr>
<th>SCPE Registries</th>
<th>Signed JRC-SCPE Collaboration Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>Site</td>
</tr>
<tr>
<td>C29</td>
<td>St. Gallen, Switzerland</td>
</tr>
<tr>
<td>C30</td>
<td>Malta</td>
</tr>
<tr>
<td>C31</td>
<td>Attica, Greece</td>
</tr>
</tbody>
</table>
6. **JRC-SCPE IT Infrastructure: Data Protection and Information Security**

Following the entry into force of the Collaboration Agreement between the JRC and the registries, the JRC has rights on the network’s central database and IT infrastructure. As a European Commission’s DG, JRC needs to comply with specific legal requirements in terms of data protection and information security.

### 6.1. Data protection

The EU Charter of Fundamental Rights (Art. 8 on human rights to privacy and protection of personal data) [11], the Treaty on the Functioning of the EU (Art. 16) [12] and the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 ‘on the protection of individuals with regard to the processing of personal data and on the free movement of such data’ [13] provide a legal framework for the processing of personal data in the EU.

The processing of personal data by EU institutions and bodies has a specific legal framework. For operating the JRC–SCPE Central Database, the JRC needs to comply with Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 ‘on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data’ [14].

The definition of personal data contained in the data protection Directive reads as follows: ‘Personal data shall mean any information relating to an identified or identifiable natural person (“data subject”); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity’.

This definition reflects a wide notion of ‘personal data’ and includes all information concerning an identifiable individual. It includes objective and subjective information, sensitive and more general information on any format.
It includes information about a person or information with the purpose of evaluating a person or information which use may have an impact on the person. [Related to]

The person may be identified by identifiers (e.g. name) or by all the means likely reasonably to be used by the controller or by any other person. [Identified or identifiable person] The information refers to living individuals with special considerations with deceased persons.

In different circumstances information may be considered not to be personal data. This is the case where the data cannot be considered to relate to an individual, or because the individual cannot be considered to be identified or identifiable. When the information that is processed does not fall within the concept of ‘personal data’, the consequence is that the Directive does not apply. This does not mean, though, that individuals may be deprived of any kind of protection in the particular situation. If the Directive does not apply, national data protection law may apply. It may therefore very well happen that certain situations not involving processing of personal data as defined in the Directive are nevertheless subject to protective measures under national law.

Processing of personal data refers to any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

The Regulation (EC) 45/2001 describes a procedure and identifies players and responsibilities in the processing of personal data in EU institutions:

- Data subjects are persons or individuals that have the rights to be protected and informed. For JRC-SCPE Central Database, the data subjects are the individual cases registered in the database.
- The Data Controller takes the responsibility of the processing. For JRC-SCPE Central Database, the Head of the Unit F.1–Health in Society is the Data Controller.
• The Data Protection Controller (DPC) advises the Controller and relates with the Commissions’ Data Protection Officer (DPO).
• The DPO approves the notification of the processing, sends the notification to the European DP Supervisor (EDPS), accepts and registers the notification.

All personal data processing operations or sets of operations in the Commission, intended to serve a single purpose or several related purposes must be notified by the controller to the data protection officer of the Commission. The information provided shall include a description of the data processing operations, security safeguards, retention period, etc.

Processing operations likely to present specific risks to the rights and freedoms of data subjects must also be declared to the EDPS. The EDPS will examine whether the processing respects the Regulation and, if the notification qualifies for prior checking, i.e. if the opinion is given prior to the start of the processing operation, will deliver an opinion within a period of two months. In his opinion, the EDPS may make recommendations to the institution or body concerned so as to ensure compliance.

6.1.1. Notification

A notification is a prior notice by the Data Controller to the Data Protection Officer of any processing operation in which personal data is involved. It contains a description of the processing operations, security, safeguards, data transfer, retention period, legal basis.

The actors involved are (Figure 3):

• The Data Controller: determines the purposes and means of the processing and is the contact person;
• Commission’s Data Protection Officer (DPO): advises and makes recommendations on rights and obligations [15];
• European Data Protection Supervisor (EDPS): independent authority, responsible that privacy rights are respected, particularly when risky processing of personal data are notified by DPO [16].
In early 2015, the Unit F.1–Health in Society prepared a notification to the DPO for processing of personal data related to JRC SCPE Central Database. The notification was prepared in collaboration with JRC-Ispra Data Protection Coordinator (DPC) and submitted to the DPO through the DPO-2 system.

The DPO sent comments to the Controller. The notification was modified to address DPO comments and resubmitted by the DPC. Following further exchange between Unit F.1–Health in Society, DPC and DPO, the notification was resubmitted [Notification 3768.1]. Figure 4 represents the workflow on the DPO-2 System for the acceptance of a notification to the DPO.

6.1.2. DPO approval–EDPS opinion

The DPO approved the notification in October 2015 and send it to EDPS. Notifications are sent to EDPS by DPO when the processing is considered of ‘high risk level 1’. Following exchanges between DPC, DPO and EDPS, the notification was considered for prior-check [Case number 2015-0982]. On 17 February 2016,
EDPS sent a request for information to the Controller. The Unit F.1 – Health in Society prepared a reply in collaboration with DPC and LISO and sent it to DPO on 26 February.

The main points of the reply to EDPS related to clarifying the purpose of the notification, providing the legal provisions for the processing, the legal agreements with the registries, detailing the functioning of registration and information to participants at the local registry level, and the risk assessment at the Central Registry level.
‘The purpose of the Notification is to cover the possibility of identifying data subjects. This possibility is only theoretical. The databases do not include data subject names or other identifiers that could be connected by the JRC to a concrete patient (that can be done only by the national registry which submitted the data to the JRC). The databases include data such as date of birth of the subject and of the mother or residence codes that in themselves do not allow for identification of an individual without an extensive effort and access to other databases, to which JRC has no access and would not allow its staff to access or combine the data in them.’

The legal basis for processing can be found in:

• Treaty on the Functioning of the EU\(^3\) (Art 168);
• Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe’s Challenges\(^1\) [Com(2008) 679 final] (5.11);
• Council Recommendation of 8 June 2009 on an action in the field of rare diseases\(^4\) (2009/C 151/02) (II.5);

The legal obligation (necessity of the processing):

• Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Implementation report [COM(2014) 548 final] on the Commission Communication on Rare Diseases: Europe’s challenges [COM(2008) 679 final] and Council Recommendation of 8 June 2009 on an action in the field of rare diseases\(^6\) (2009/C 151/02);

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* European Union Committee of Experts on Rare Diseases Core Recommendations on Rare Disease Patient Registration and Data Collection to the European Commission, Member States and all stakeholders (EUCERD, 5 June 2013);
* Administrative Arrangement between DG SANCO and JRC on the European Platform for Rare Diseases Registration [17.030600/13/669748].

Functioning of the *registration and information to patients*: ‘The registries are the only ones who collect data from the patients/cases (the JRC has no contact with the patients). The registries, at their local, regional or national level are responsible for obtaining the necessary approvals and for complying with the institutional and national requirements on data protection. The fact that they transmit the data annually to the JRC-SCPE Central Registry is implicitly the confirmation of their compliance with their national legislation’.

On the 17th June 2016 the EDPS issued a Prior Checking Opinion which stated that there is no reason to believe that there is a breach of the provisions of the Regulation. However, EDPS requested further information and documentation from the JRC to be provided within a period of three months, to demonstrate that the EDPS recommendations have been implemented.

In particular, JRC was asked to inform the EDPS about the feasibility of the adoption of a delegated act and/or of any other alternative means which can establish the lawfulness of the processing of data related to health under analysis. Moreover, the EDPS asked to make an assessment as to whether historical data are still necessary for its present and future scientific research, analysis and reports, and to set out a maximum retention period for the data. JRC was also requested to prepare a privacy notice and ensure that the national registries include a link to the JRC privacy notice in the information which is provided to the participants enrolling in the national registries. Finally, the EDPS requested JRC to carry out a security risk assessment for SCPE.

The reply to the EDPS was prepared and sent on the 17th September, including a revised version of the notification, the privacy notice, and the security documents.

The notification was finally published on the 27th October 2016 in the Register of the Data Protection Officer and is accessible online. It is now at the last stage of EDPS approval. *Table 7* shows the DPO-2 History log of Notification 37681.

**Table 7.** History of Notification 37681 on the DPO-2 system.

<table>
<thead>
<tr>
<th>Profile</th>
<th>Status</th>
<th>Date</th>
<th>Action</th>
<th>Due date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPO</td>
<td>Final</td>
<td>27/10/2016</td>
<td>Publication in the DPO Registry</td>
<td>–</td>
</tr>
<tr>
<td>Controller</td>
<td>EDPS Validation</td>
<td>16/09/2016</td>
<td>Reply to EDPS</td>
<td></td>
</tr>
<tr>
<td>DPO</td>
<td>EDPS Validation</td>
<td>17/06/2016</td>
<td>Prior Checking Opinion</td>
<td>–</td>
</tr>
<tr>
<td>DPO</td>
<td>EDPS Validation</td>
<td>29/01/2016</td>
<td>Validation by the DPO</td>
<td>–</td>
</tr>
<tr>
<td>DPC</td>
<td>DPO Validation</td>
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<td>Validation approved by DPC</td>
<td>11/11/2015</td>
</tr>
<tr>
<td>Controller</td>
<td>DPC Validation</td>
<td>13/10/2015</td>
<td>Review by the controller</td>
<td>08/04/2015</td>
</tr>
<tr>
<td>DPO</td>
<td>Comments/Review</td>
<td>09/03/2015</td>
<td>Validation rejected by DPO for major modifications</td>
<td>08/04/2015</td>
</tr>
<tr>
<td>DPC</td>
<td>DPO Validation</td>
<td>05/03/2015</td>
<td>Validation approved by DPC</td>
<td>01/04/2015</td>
</tr>
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<td>04/03/2015</td>
<td>Completed</td>
<td>01/04/2015</td>
</tr>
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<td>DPC</td>
<td>Draft</td>
<td>04/03/2015</td>
<td>Draft created</td>
<td>01/04/2015</td>
</tr>
</tbody>
</table>

### 6.2. Information security

The JRC-SCPE Collaboration Agreement reads that the JRC-SCPE ‘Central Registry undertakes to put in place appropriate technical and organisational security measures having regard to the risks inherent in the processing, to the nature of the personal data concerned and in line with the rules and regulations applicable to it in order to:

(a) prevent any unauthorised person from gaining access to computer systems processing personal data, and especially:

(b) unauthorised reading, copying, alteration or removal of storage media;

(c) unauthorised data input, as well as any unauthorised disclosure, alteration or erasure of stored personal data;

(d) unauthorised use of data-processing systems by means of data transmission facilities;

(e) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;

(f) record which personal data have been communicated, when and to whom;

(g) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation.’

‘The Central Registry applies the following rules and standards on Security of Information Systems:


• Commission Decision of 16 August 2006 C(2006)3602 concerning the security of information systems used by the European Commission [18].


The Commission Decision’s, Implementing Rules and related Standards and Guidelines provide for security measures for the protection of the involved information systems and the information processed therein against threats to their availability, integrity and confidentiality.

The legal provisions apply to all Directorates-General and departments in all places of work, including the Joint Research Centre and the delegations in third countries, offices linked administratively to the Commission and all Executive Agencies or other bodies using the Commission’s information systems.
To comply with the legal requirements, the responsible of the Information System must start by performing a proper Business Impact Assessment (BIA) and Risk Analysis (RA) to ensure sufficient and appropriate security measures are in place. Based on the BIA and RA, the responsible of the Information System may end-up by elaborating an IT Security Plan (ITSP).

At JRC-Ispra, the JRC Local Information Security Officer (LISO) coordinates information and communications technology (ICT) security and adapts the Commission standards and guidelines on ICT security to the JRC.

The Unit F.1 – Health in Society has an IT team that supports the Rare Diseases team with IT competences.

6.2.1. Security plan

In close collaboration with JRC LISO, the Unit F.1 – Health in Society addressed all information security issues related with JRC-SCPE Information System (Figure 5).

The security needs and the business impact analysis was summarised in the Business Impact Assessment document. Based on the BIA findings, the JRC-SCPE Information System was classified in terms of confidentiality, integrity and availability (CIA) and as a whole:

• Confidentiality Limited High.
• Integrity Critical.
• Availability Moderate.
• Classification SPECIFIC.

The classification process is used to classify all physical and logical assets based on the classification of the information they are storing or processing. The classification is aimed at establishing the business impacts for the Commission of a loss of confidentiality, integrity and availability of its information and at synthesising these impacts in classification levels.

A system is classified as ‘SPECIFIC’: 
• With a confidentiality level of LIMITED HIGH or above, and integrity and availability levels of STRATEGIC or CRITICAL; or
• handling EU classified information; or
• handling personal data falling under Articles 10 or 27 of Regulation (EC) No 45/2001.

The level of rigour to be applied during the risk assessment depends upon the CIA classification associated with the system.

The JRC-SCPE Information System was classified as SPECIFIC and required a detailed and documented Threat and Vulnerability assessment.

The JRC prepared the following documents which were approved by LISO:

• Business Impact Assessment.
• Scope of Security of the System.
• Implementation Plan.
• Security Plan.

Figure 5. JRC-SCPE Information System security framework.
The added value of the SCPE network of registries comes from the pooling of standardised data into the Central Database to perform monitoring and research activities. The JRC-SCPE Central Database (CDB), component of the JRC-SCPE Central Registry fully operates at the JRC since December 2016.

The operation of the CDB includes all activities aimed at strengthening the value and quality of the CDB. This comprises, among other functions, maintaining the CDB, updating the CDB annually with data submissions from registries, and extending the network of data providers.

After entering into force of the Collaboration Agreement, the Unit F.1–Health in Society performed several activities to enable full functionality of CDB at JRC, including the set-up of the JRC-SCPE IT infrastructure, and the management of the data submission campaign in 2016. The transfer from the Centre in Grenoble to the JRC of the complete CDB with all cases collected since 1998 was done in December 2016.

7.1. SCPE Information System

The transfer of the SCPE Central Database did not consist only of a simple transfer of data files and procedures for managing and analysing the data, but it necessitated the creation of an information system that satisfies the strict requirements for IT data management systems maintained at the European Commission (EC).

The JRC-SCPE Information System currently implemented is presented in the scheme on Figure 6 and can be divided into three macro-processes:

A. Data acquisition.
B. Storage and management of data.
C. Access rules and transfer of data to third parties.
The implementation of this system required formal approval by the information security officer (LISO) (see section 6.2 for details), compliance with data protection rules of the EC and a prior check opinion by the European Data Protection Supervisor (EDPS) (see section 6.1 for details).

Figure 6. Schematic presentation of the IT system for SCPE data transmission and management implemented at JRC.

The data transmission by the registries is done through a portal developed by the IT Support Group of the Unit F.1 – Health in Society. This portal was used for the first time in the SCPE data submission campaign in July 2016.


7. JRC-SCPE Central database – part of the European Platform for Rare Diseases Registration
Starting from the existing SCPE portal in Grenoble, a new portal was created. The portal is entirely managed by the JRC and includes several functionalities. Among these functionalities there is a system for automatic checks performed on the files sent by the registries.

The system generates a report of formal errors occurring during the transmission (structural checks) and of the consistency of the values in the reported variables (consistency checks). These errors have to be corrected by the registry in order to validate the files. Once validated the file is included in the portal. This system for automatic checks was extended by the JRC in respect to the checks present in the previous SCPE portal.

The access to the portal for data transmission is granted to the registries via the ‘EU Login’ accounts. Each registry has a separate ‘EU Login’ account in order to guarantee traceability of the access and safety of data transmission.

7.2. Updates of the CDB – annual data collection

To achieve the main purpose of surveillance of cerebral palsy in Europe, the CDB needs to be regularly updated by registry members. The SCPE network established a calendar for performing all tasks necessary to achieve its main objective.

Historically the network had one annual data collection campaign, during the spring time. The data were collected based on a set of variables defined in the ‘Guideline for data submission’ developed by the network. This is a guidance document aimed at enabling registries to prepare files of CP cases and population-based denominators to be submitted to the SCPE Common Database, in accordance with the SCPE agreed definition and inclusion criteria, the predefined format for the requested items.

Data checks and validation followed and ‘feed-back to registries’ documents were prepared for the one day meeting of the Data Working Group (usually in June). Registry members worked in July-September on the feed-back they received from SCPE Common Database in late June, and discussed them at the Annual Plenary meeting planned in October-November.
7.2.1. First data submission campaign coordinated by JRC

The first data submission campaign coordinated by the JRC-SCPE Central Registry took place in 2016. In preparation of the campaign, a meeting took place in April 2016 between JRC and Grenoble staff members and focused on the revision of functionalities of the data portal developed at JRC and on practical planning of further steps for data collection.

During that meeting JRC received paper copies of the following documents which describe the current data management done by the SCPE network, from the planning of the data submission campaign to the loading of this data into the Central Database once it is validated by the JRC-SCPE Central Registry:

1. **Data submission campaign.** Standard Operating Procedure No. 1 (SOP1) – SCPE network – V 1.4 February 2015.
2. **Quality checks.** Standard Operating Procedure No. 2 (SOP2) – SCPE network – V 1.0 April 2015.
3. **Data validation and Database management.** Standard Operating Procedure No. 3 (SOP3) – SCPE network – V 1.0 March 2015.
4. **Feedback to the registers and network.** Standard Operating Procedure No. 6 (SOP6) – SCPE network – V 1.0 February 2015.
5. **Summary table of cases and denominators expected for every register in 2015 data submission** (updated later for the 2016 data collection campaign on specific request of the JRC).

During the campaign the local registries transmitted data through the JRC-SCPE data transmission portal. The data collection campaign of the cases born in 2007 was opened by an email sent from the JRC-SCPE@ec.europa.eu functional mailbox on the 22nd June 2016.

Due to the introduction of new variables and the changes in some pre-existing checks, the JRC-SCPE portal was modified until 7th July 2016. The system of automatic checks was reviewed by the network members from Grenoble during a meeting held at JRC on the 5th July 2016. The Data Working Group updated also the ‘Guideline for data submission – Version 2016’.
In order to permit to the registries to create the files for the submission with the updated guidelines the deadline for the data submission was fixed to 31st August 2016. Since this was the first data collection managed by the JRC and many registries had practical questions concerning the use of the portal, the data transmission was practically allowed until the 30th September 2016.

The registries that participated in the first data submission campaign led by JRC are reported in Table 8. It has to be noted that some registries send data for more birth years than just 2007. An overview of all the data received is shown in Figure 7.

<table>
<thead>
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7.2.2. Collaboration with University of Grenoble during the first data submission campaign

The tasks to be performed by the JRC-SCPE Central Registry during the annual data collection campaign can be summarized in the following steps:

1. Saving the original files collected from the registries (implementation at JRC: the files are saved automatically on a secure server).
2. Carry out checks using the STATA programme.

Figure 7. Number of cases submitted (for the various birth years) in 2016 to the JRC by the registries.

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3. Evaluation of the results produced by the programme (descriptive analysis) to identify coding anomalies to be clarified with the registries in order to achieve a correct and definitive record of all cases.
4. Loading of the validated data into the Access Central Database.
5. Preparation of the feedback for the registries for the annual plenary meeting.

The validation of data mentioned above in step 3 requires clinical evaluation of the descriptive variables and check of their coherence with other collected items. Since JRC does not have the relevant competences to perform this step, it was necessary to have the support from clinical experts for this activity.

To put in place such collaboration, two conditions had to be fulfilled:

1. To initiate a service contract for the revision of the coding by clinical experts.
2. To enable the transfer of the necessary data for validation by the contractor from the JRC.

The service contract for the revision of the coding by clinical experts was signed in October 2016 with the company Floralis based in Grenoble.

Concerning the transfer of files for validation by the experts, from the moment the data collection is carried out by the JRC, the data management is subject to security constraints and confidentiality procedures defined by the Local Informatics Security Officer (LISO). In the current procedures that are partially in common to the data management of other health information systems implemented in the Unit F.1 – Health in Society, the automatic transmission of data to third parties can be made via secure connections such as sftp or ftps.

The IT support team has discussed at length with the University of Grenoble the best way for secure data transfer. Finally, at the end of October 2016 a technical solution was found that meets the required security criteria for the exchange of individual data. Also, a formal definition of the minimum data set of variables to be transferred was done, as according to the data protection rules the variables transferred must be only those necessary for the scope for which they are used.
7.2.3. Analysis of data submitted for birth year 2007

The data received from all registries were processed during the first week of October 2016 using the STATA software, according to the standard Operating Procedure (SOP2) received from Grenoble.

Before performing the descriptive analysis the data received were used to verify that the automatic constraints checks implemented in the JRC-SCPE portal worked properly. Indeed, the evaluation showed that a revision of one of the checks was necessary.

The descriptive analysis was also performed creating MS Access queries and R programming to compare the results with the STATA ones. This additional step was done to judge if the program for the descriptive analysis could in the future be implemented in the IT system, in order to create automatic reports together with a selected variable for further evaluation, using open source programs available in the IT environment for data management at the JRC.

The automation of this step for data revision would greatly improve the efficiency of the work because it permits to identify in the files the variables that are needed for the validation of the cases at the time when the files are uploaded in the portal by a Registry, while the execution of the descriptive analysis manually is time consuming.

The obtained STATA results were sent to the contractor at the University of Grenoble, where further checks of all the variables were done. Any inconsistencies, errors or questions regarding the variables were then discussed directly with the involved registries, until the files were regarded ready to be uploaded into the Central Database at JRC.

7.3. Transfer of the Central Database to JRC

The data were transferred from Grenoble to JRC on the 12th December 2016 in the format of an MS Access file, containing 17372 cases collected until the 2015 data submission (see Table 9). Previously, Grenoble sent also the denominators for the active registries (21 Excel files).
Table 9. Summary of data transferred from Grenoble to JRC in December 2016, by registry and years of birth

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7. JRC-SCPE Central database – part of the European Platform for Rare Diseases Registration
In addition, JRC received seven previous versions of the data submission guidelines, and a table with the description of the associated variables used in the previous data submission campaign.

A contract was awarded to University of Toulouse for the preparation of documentation (SOPs and guidelines) that describe accurately the data management and data analysis procedures in the Central Database.
The SCPE network developed a website[^10] for SCPE-NET project/operating grant (2009-2014). The website contents include public information about SCPE and SCPE Reference and Training Manual (RTM) accessible only with prior registration. In addition the website has a private part for members. The IP rights of the website contents are on SCPE network.

Content management is coordinated by SCPE working group for web-dissemination led by Sandra Julsen-Hollung (CP Registry of Norway).

The website has multilingual functionalities. All contents are available in English, parts of the public part and the RTM are available in German and Portuguese. The Swedish version is in test phase, the Latvian version of the website is advanced.

The website is hosted by an IT firm (Innovatif, Slovenia), until 2015 under yearly contract with SCPE-NET coordinating centre in Madrid. This is the same IT firm that designed and developed the website.

According to the JRC-SCPE Collaboration Agreement, ‘the Registries shall grant the JRC an exclusive and royalty-free licence to manage the SCPE website (http://www.scpenetwork.eu) for the performance of the actions required by this Agreement. The JRC may at its choice install and host the website on its servers or resort to third-party hosting services. The JRC may make copies of the website for back-up and archival purposes, provided that the JRC maintains on this copy all the proprietary notices which appear on or in the contents of the website. The JRC or its sub-licensees may amend, modify, translate, decompile, dissemble, and create derivative works based on the website for the purposes established in this Agreement. The JRC may sublicense any of the granted rights regarding the website or any portions thereof to any third party provided that the exercise of said rights are maintained within the purposes established by the Parties to this Agreement’.

[^10]: http://www.scpenetwork.eu
The following sections cover what Unit F.1–Health in Society has done and is planning to do in relation to the SCPE website.

8.1. Website registration

All JRC and JRC-hosted websites have to be recorded in the JRC web registry, as well as FTP sites and web services and third-party websites hosted or maintained by the JRC.

The JRC Website Registry is an information system set up to meet the following aims:

• maintain an accurate and detailed inventory of all JRC websites and services, as well as third-party websites hosted or maintained by the JRC,
• improve consistency and quality control of these websites, including compliance with data protection and IT security rules,
• monitor each website project from the definition of website requirements to the launch and maintenance of the website, up to its archival and decommissioning,
• help rationalising the JRC web-presence by avoiding unnecessary multiplication of JRC websites.

The steps for recording the website are:

• Definition and Development.
• Approval and Validation.
• Allowance and Compliance.
• Activation and Production.
• Revalidation and Deactivation.

Different roles are identified for the recording:

• Site Owner or project leader.
• Web Master or web administrator.
• Head of Unit.
• The Global Controllers:
- Communication Unit/DG (COM),
- Communication Correspondent (COCOM),
- Local Informatics Security Officer (LISO),
- Intellectual Property Rights Unit (IPR),
- Data Protection Coordinator (DPC),
- Information and Communication Technologies Unit (ICT).

The outcome of the registration process is a clear understanding of website related ownership, data protection, information security and intellectual property rights and a full compliance with Commission’s requirements, also in terms of communication objectives and visual identity.

The Unit F.1–Health in Society is planning to start the registration process of a new SCPE website under the url http://scpe-network.jrc.ec.europa.eu. Figure 8 summarises the website registration process.

1. The new site is relevant (COM)

2. URL not conflicting with other JRC activities (COCOM)

3. Website complies with JRC communication objectives (COCOM)


5. Website complies with JRC IT Security Policy (LISO) → Security Plan

6. Website complies with Copyright rules (IPR) → IP rights

7. Website complies with Data Protection rules (DPC)

   → Website recorded on JRC Website Registry

8. All required technical parameters are known, Website is activated (ICT)

Figure 8. The JRC website registration workflow.
8.2. Next steps on website management

In order to transfer the website to the JRC, it is necessary to follow the website registration workflow, prepare necessary documentation and make changes to the website visual identity to be compliant with the European Commission’s web registry rules. The SCPE Website and Dissemination Working Group considered that this is a good occasion to introduce additional modification and updates to the website, to render the SCPE website more modern and attractive, and increase the dissemination of scientific network’s results.

The new version of the website should be released in the second half of 2017. Until all the required adaptations and changes of the JRC-SCPE website are completed and the website is registered in the JRC web registry, the current SCPE website will continue to be maintained at Innovatif. A service contract with Innovatif for the hosting and maintenance of the website in 2017 is planned.
9. JRC-SCPE Coordinating Activities

9.1. JRC-SCPE Management Committee

Following the entry into force of JRC-SCPE Collaboration Agreement, JRC-SCPE Management Committee (MC) was established to coordinate the execution of the activities under the Agreement.

The Management Committee shall meet in person at least three times a year. Additional meetings may be arranged via tele/videoconference. In 2016 three JRC-SCPE Management Committee meeting took place: on 7th March, 4th July and 16th November (in relation with the SCPE Annual Plenary meeting).

9.2. Working groups

SCPE Network developed a multi-annual planning (2013-2016) and a series of topics are selected and constitute the programme of work. In the last work plan the focus was on:

1. Sustainability of the network.
   • Maintain and develop central database.
   • Harmonisation, Uniformity of definitions.
   • Data quality assurance and validation assessment.
   • Transfer of the current Central Database to the EU Rare Disease Platform.
   • SCPE website.
   • SCPE annual meeting.
   • Site-visits to new registries.

2. Public health.
   • Monitor trends, determinants and outcomes in individuals with cerebral palsy.
   • Increase the accessibility to SCPE epidemiological data, and to best practices in clinical information, to develop standard tables with pooled data which could be available on the public part of the website.
3. Research activities and International activities.
   • Contribute to the planning of and participation in scientific events.
   • Revision of data request and authorship documents.
   • Develop and test collaboration with health economist in EU and EEE countries.
   • Prospective exercise for future projects.

The activities of the work programme are developed and supervised by the SCPE working groups. Some topics are addressed horizontally by several WGs.

9.2.1. SCPE Data Working Group

The Data WG plans the data submission campaign, assesses data quality, and proposes further harmonisation.

The Data WG includes clinical and epidemiological expertise. Representatives from SCPE Central Database Centre in Grenoble are an important part of the Data WG. A person from the JRC-SCPE Central Registry is also member of the Data WG. The Data WG provides critical input to SCPE Reference and Training Manual, and to data related Guidelines and Standard operating Procedures.

Following the decisions of JRC-SCPE Management Committee, the JRC-SCPE Central Registry prepared with the Data WG the practical steps for transferring and operating SCPE Database.

9.2.2. SCPE Website and Dissemination Working Group

The main tasks of the Website and Dissemination WG are to develop dissemination contents and to increase visibility of website contents. An important ongoing activity of the WG is the development of public health indicators obtained from SCPE Database. A person from the JRC-SCPE Central Registry is member of the Website and Dissemination WG.

In 2016 the WG had a meeting on the 14th October at JRC in Ispra to discuss all the steps that need to be accomplished before the website can be registered in
the EC website repository and officially transferred to JRC. This includes the adaptation to the new visual identity, but also legal issues related to copyrights, IP rights and ownership. The outcome of the meeting was a design for a new website and a detailed work plan for 2017. Members of the WG plan to revise the current web-pages and/or draft text for new web-pages. The new version of the website should be released in the second half of 2017.

On the occasion of the International CP Conference that was held in Stockholm on 1-4 June 2016, the JRC in collaboration with the SCPE Website and Communication working Group prepared a leaflet on the SCPE activities. The printed version is available for distribution at international conferences and the .pdf version is accessible on the SCPE website for download.

9.2.3. SCPE Scientific Activities Working Group

The Scientific Activities WG promotes SCPE research activities and international collaborations.

The JRC supported and funded the organisation of a meeting in Varese (9th November 2015) on the development of the Europe/Australia EUROCAT/SCPE study on congenital anomalies and cerebral palsies.

9.3. Annual Plenary meeting

Since it was established in 1998, SCPE network organises every year the SCPE Plenary meeting. It is the major SCPE annual event where registry leaders, representatives and contributors can share and exchange experiences and practices.

The SCPE Plenary meeting is also an important event for disseminating network and registries activities. This is one of the reasons why the organisation of the plenary used to rotate between member registries.

According to the Collaboration Agreement, the JRC-SCPE Central Registry has the responsibility to supervise and support the organisation of the annual Plenary Meeting. The JRC organised two JRC-SCPE Plenary meeting in 2015 and in 2016.
9.3.1. JRC-SCPE Plenary meeting in 2015

Before the entry into effect of the Collaboration Agreement, the JRC organised the SCPE 17th Annual Plenary Meeting on 9-11 November 2015.

Registry Leaders from all member registries were invited to the Annual Plenary Meeting and representatives of 22 registries from 18 European countries attended the meeting. In addition, invited speakers from SCPE collaborating organisations and European Commission representatives from DG SANTE and JRC also participated in the meeting. Overall, 53 participants attended the SCPE plenary meeting in Varese. The JRC covered all organisational costs and fully funded one representative per registry and the invited speakers.

The main aim of the meeting was to progress in preparing the transfer to the JRC. Other aims were to strengthen the network’s scientific activities and registration practices.

The frame of the collaboration between the JRC and the SCPE was set with presentations on the JRC and its public health activities and on the EU health information strategy. The EU Platform on Rare Disease (RD) Registration was presented in the context of EU regulatory developments on RD.

The JRC-SCPE Collaboration Agreement was presented as a legal framework for the transfer and hosting of SCPE CDB at the JRC and for the support by JRC to SCPE coordinating activities. Key principles of the Collaboration Agreement were outlined: registries remain owners of their data and the continuity of previous work is coordinated by the MC.

It was agreed that following the entry into effect of the Agreement, relevant data will be transferred to JRC-SCPE Central Registry which will operate 2016 data submission campaign.

The preparatory work being performed in view of the transfer was presented: a new data submission web portal had been developed by JRC and SCPE was completing guidelines and operating procedures.
SCPE had continued to work towards interoperability of registry data by further harmonising classification systems with international partners. Recently the emphasis had been on neuroimaging classifications and inclusion and exclusion criteria. The development of data quality and public health indicators and an easier access to SCPE results by including output tables on the website and guidance on its interpretation were planned. It was considered that the involvement of patients and families should continue to be a priority in SCPE activities.

Recent scientific activities of the network include the publication and preparation of papers, the starting up of research projects and the contributions to the programme of the major conferences in the childhood disability field.

It was concluded that the JRC would provide a sustainable framework and major input to quality data processing, integration with other information systems, and dissemination of results, particularly to policy makers.

9.3.2. JRC-SCPE Plenary meeting in 2016

The next SCPE Plenary meeting in 2016 was organised by JRC on 14-16 November in Baveno (Italy). There were 50 participants representing 21 SCPE registries, and other organisations (patient organisation La Fondation Motrice in France, Cerebral Palsy Integrated Programme (CPIP) programme in Scotland).

The programme of the meeting was developed together with the JRC-SCPE Management Committee. In the first session, messages from the JRC were transmitted supporting the collaboration between JRC and the SCPE network and the strong position of the SCPE in the European Platform for Rare Diseases Registration.

The report from JRC-SCPE Central Registry presented the work done at the JRC since the last meeting including legal, data protection, information security issues, as well as information systems developments and the proposal for a new JRC-SCPE website.

The JRC also stressed the absolute need to complete the transfer of the SCPE Central Database (CDB) from the University of Grenoble to the JRC by the end of the year. The transfer of the CDB is fundamental for the complete handover
of the SCPE European-level coordinating activities to the JRC and is the crucial part of the collaboration agreement between JRC and the SCPE network (in force since January 2016).

The central session of the meeting was dedicated to the analysis of the data submitted this year by the SCPE registries to the JRC. The analysis was done for the first time by the JRC in collaboration with the University of Grenoble.

Other sessions covered updates from SCPE registries and presentations from new potential network members, new SCPE studies and scientific collaborations, revision of some SCPE guidelines (authorship, data requests, materials for new applicants, on-site validation visits). Parallel sessions with meetings of the three working groups (Website and Dissemination WG, Data WG and Scientific Activities WG) took place. Each group revisited its composition (new members joined), reviewed the current activities and defined a work plan for 2017.

9.4. Communication

The JRC-SCPE Central Registry is operating a functional mailbox [JRC-SCPE@ec.europa.eu], which is used both for internal communication between the JRC-SCPE Central Registry and the network members, but also for external queries. The JRC-SCPE Central Registry staff assesses and answers the members and external queries on a daily basis, and if considered necessary, forwards the questions to the management Committee members.

The JRC-SCPE Central Registry is also planning to develop a direct channel of communication with SCPE Member registries, i.e. a periodical communication by email.
10. Conclusions

The development of the European Platform on Rare Diseases Registration, as agreed between DG JRC and DG SANTE, started with a comprehensive activity in order to secure a sustainable solution for the internationally recognised, long-lasting network of 31 population-based registries for the surveillance of cerebral palsy in Europe, SCPE.

The transfer of the European-level coordinating activities of SCPE to the JRC was an intensive and complex process carried out over about two years. In addition to achieving the objective of having in place and operational at the JRC the new JRC-SCPE Central Registry, the intense exchanges with SCPE representatives—members of the former Steering Committee, registry leaders, members of working groups—was an enriching experience, giving us valuable insights into their scientific work done with highest expertise and dedication over several decades.

The work on this transfer turned out to be an opportunity for a concerted action between different services of the Commission/JRC. The result could be achieved due to the continuous and fruitful involvement of the legal advice Unit, IT support group, local information security office, intellectual property rights office, data protection coordinator, procurement service.

Overall, this process was not a simply ‘transfer’, but the establishment of a whole new system, with new structures, which often required to go in minute detail of the topics addressed. It was a challenging experience which, most importantly, builds the fundament for continuing the work on the surveillance of cerebral palsy in Europe. Bringing together the information of the registries involved, the output of the JRC-SCPE Central Registry provides a source of knowledge for healthcare providers, patients, researchers, policy makers, as well as for the general public.

The next steps in giving added-value to SCPE data will be to put this data in the wider context of health and health-related data in the context of European health information systems.
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<td>CP</td>
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<td>DG SANTE</td>
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<td>DP</td>
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<td>European Data Protection Supervisor</td>
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