

## Operational criteria for the evaluation of European Reference Networks (“ERNs”)

| AREA 1. GOVERNANCE AND COORDINATION |                                                                                                                        |                                                                                                                                                                                 |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1                                 | The ERN has established a clearly defined governance framework that ensures appropriate ERN coordination and oversight |                                                                                                                                                                                 |
| Measurable Elements                 |                                                                                                                        |                                                                                                                                                                                 |
|                                     | 1.1.1                                                                                                                  | The structure and the implementation of the rules of procedure of the ERN's coordination board have facilitated the organization of tasks and the incorporation of new members. |
|                                     | 1.1.2                                                                                                                  | An efficient coordination structure to support the ERN is in place to assist the governing bodies in reporting, quality improvement, evaluation, meetings and other activities. |
|                                     | 1.1.3                                                                                                                  | Mechanisms to maintain or enhance the level of collaboration among the ERN members as well as their affiliates have been put into practice.                                     |
|                                     | 1.1.4                                                                                                                  | Healthcare Providers (“HCPs”) have been involved for specific ERN-related tasks, sharing responsibilities among all the Members of the ERN.                                     |
| 1.2                                 | The ERN has developed regular evaluation and monitoring processes enabling the assessment of the ERN’s progress        |                                                                                                                                                                                 |
| Measurable Elements                 |                                                                                                                        |                                                                                                                                                                                 |
|                                     | 1.2.1                                                                                                                  | An ERN dashboard or similar has been implemented to monitor the activity, outcomes, and initiatives of the ERN and its Members.                                                 |
|                                     | 1.2.2                                                                                                                  | There is an internal assessment of HCPs' participation.                                                                                                                         |
|                                     | 1.2.3                                                                                                                  | HCP professionals' satisfaction with the performance of the ERN is periodically evaluated.                                                                                      |
| 1.3                                 | The ERN has established mechanisms for the integration of patient organizations in the strategic actions               |                                                                                                                                                                                 |
| Measurable Elements                 |                                                                                                                        |                                                                                                                                                                                 |
|                                     | 1.3.1                                                                                                                  | Patient representatives have been included in the governance framework of the ERN.                                                                                              |
|                                     | 1.3.2                                                                                                                  | The Board has incorporated the opinion of patients and their caregivers (including families) when outlining strategies.                                                         |
|                                     | 1.3.3                                                                                                                  | Patients and support groups are major stakeholders in ERN-related activities.                                                                                                   |
|                                     | 1.3.4                                                                                                                  | The ERN monitors and evaluates the involvement of patients in the activities of the ERN.                                                                                        |
| 1.4                                 | The ERN has implemented actions to ensure the sustainability of the ERN                                                |                                                                                                                                                                                 |

| AREA 1. GOVERNANCE AND COORDINATION |       |                                                                                                                                                   |
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| Measurable Elements                 |       |                                                                                                                                                   |
|                                     | 1.4.1 | The ERN has identified goals, opportunities, and threats for the future.                                                                          |
|                                     | 1.4.2 | The ERN has evaluated its own organizational and economic viability.                                                                              |
|                                     | 1.4.3 | The ERN has developed a financial plan to meet its objectives including funding efforts and a justified distribution of resources across members. |
|                                     | 1.4.4 | The ERN has ensured its connection with other existing networks, authorities, health systems, etc. for its long-term sustainability.              |

| AREA 2. CLINICAL CARE |                                                                                                                                                           |                                                                                                                                                                                                                                                                                 |
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| 2.1                   | The ERN has developed a strong clinical care management strategy: Clinical guidelines, care pathways and best practices for clinical care and transitions |                                                                                                                                                                                                                                                                                 |
| Measurable Elements   |                                                                                                                                                           |                                                                                                                                                                                                                                                                                 |
|                       | 2.1.1                                                                                                                                                     | The ERN has developed or adapted (from other sources) and disseminated clinical guidelines and other types of clinical decision-making tools in collaboration with the HCPs.                                                                                                    |
|                       | 2.1.2                                                                                                                                                     | The ERN has implemented guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.                                                                                                     |
|                       | 2.1.3                                                                                                                                                     | The ERN has developed recommendations for care pathways based on the needs of patients, clinical evidence, and on the available organizational, professional, and technological resources.                                                                                      |
|                       | 2.1.4                                                                                                                                                     | The ERN has worked on recommendations for cross-border care pathways to assure equality in the access to care within its area of expertise, according to the legislation applicable.                                                                                            |
|                       | 2.1.5                                                                                                                                                     | The ERN follows up the implementation of recommendations for care pathways to encourage consistent use across its Members.                                                                                                                                                      |
|                       | 2.1.6                                                                                                                                                     | Guidelines, recommendations for care pathways, and protocols are rechecked and updated if needed at least every three years.                                                                                                                                                    |
| 2.2                   | The ERN has implemented a multidisciplinary approach to care                                                                                              |                                                                                                                                                                                                                                                                                 |
| Measurable Elements   |                                                                                                                                                           |                                                                                                                                                                                                                                                                                 |
|                       | 2.2.1                                                                                                                                                     | The ERN has implemented a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.                                                                                                                                                 |
| 2.3                   | The ERN has established mechanisms for the integration of eHealth and Information and Communication Technologies (ICT) clinical tools                     |                                                                                                                                                                                                                                                                                 |
| Measurable Elements   |                                                                                                                                                           |                                                                                                                                                                                                                                                                                 |
|                       | 2.3.1                                                                                                                                                     | The ERN promotes the use of technologies such as telemedicine, e-Health records, remote consultation, health information portals, electronic transfer of prescriptions, multidisciplinary e-Meetings designed according to the needs and requirements of patients and families. |
|                       | 2.3.2                                                                                                                                                     | The ERN has implemented the CPMS to share clinical data, images, and additional information. If the ERN uses any other system, this should be compatible in all its centres and must meet national and European legal requirements.                                             |

| AREA 3. QUALITY AND PATIENT SAFETY |                                                                                                                               |                                                                                                                                   |
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| 3.1                                | The ERN has defined a quality and patient safety strategy                                                                     |                                                                                                                                   |
| Measurable Elements                |                                                                                                                               |                                                                                                                                   |
|                                    | 3.1.1                                                                                                                         | The strategy includes specific objectives and recommended activities for their achievement.                                       |
| 3.2                                | The ERN has implemented quality and patient safety indicators to monitor clinical processes, performance and outcomes of care |                                                                                                                                   |
| Measurable Elements                |                                                                                                                               |                                                                                                                                   |
|                                    | 3.2.1                                                                                                                         | The ERN has selected a pool of measures (indicators) to monitor clinical processes, performance and outcomes of care.             |
|                                    | 3.2.2                                                                                                                         | The indicators are periodically reported, and the information is used for collective reflection on outcomes to learn and improve. |

| AREA 4. PATIENT CENTRED CARE |                                                                                                 |                                                                                                                                                                           |
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| 4.1                          | The ERN has implemented mechanisms to empower patients through patient education and engagement |                                                                                                                                                                           |
| Measurable Elements          |                                                                                                 |                                                                                                                                                                           |
|                              | 4.1.1                                                                                           | Educational resources for patients addressing disease management, coping skills and other practical skills, have been developed and disseminated.                         |
|                              | 4.1.2                                                                                           | The ERN produces tailored information on patient safety standards and safety measures for patients and their caregivers (including families) to reduce or prevent errors. |
| 4.2                          | The ERN has developed strategies for patient involvement                                        |                                                                                                                                                                           |
| Measurable Elements          |                                                                                                 |                                                                                                                                                                           |
|                              | 4.2.1                                                                                           | The ERN collaborates with patient organisations to develop and implement care pathways, guidelines, protocols, and indicators.                                            |
|                              | 4.2.2                                                                                           | The ERN has undertaken initiatives to improve the safety and quality of care in collaboration with patient organizations.                                                 |
| 4.3                          | The ERN has implemented actions to measure and learn from patient experience                    |                                                                                                                                                                           |
| Measurable Elements          |                                                                                                 |                                                                                                                                                                           |
|                              | 4.3.1                                                                                           | The ERN has established a standardised common tool or methodology for measuring the patient and family experience.                                                        |
|                              | 4.3.2                                                                                           | The ERN periodically evaluates the needs and barriers to care experienced by patients and families and uses this information to implement actions to improve care.        |

| AREA 5. CONTRIBUTION TO RESEARCH |                                                                                                                    |                                                                                                                                                                                                                     |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                              | The ERN has implemented strategic actions to fill research gaps and promote innovation in medical science          |                                                                                                                                                                                                                     |
| Measurable Elements              |                                                                                                                    |                                                                                                                                                                                                                     |
|                                  | 5.1.1                                                                                                              | Research gaps and opportunities have been identified and a research agenda has been developed.                                                                                                                      |
|                                  | 5.1.2                                                                                                              | The ERN has actively involved patients and other stakeholders in identifying research gaps and developing the agenda.                                                                                               |
|                                  | 5.1.3                                                                                                              | The ERN maintains ongoing technical oversight and discussions with Members to closely monitor and provide feedback of the research throughout the process.                                                          |
|                                  | 5.1.4                                                                                                              | The ERN implements actions to provide the future workforce with knowledge and skills to lead research.                                                                                                              |
| 5.2                              | The ERN has developed a framework for collaborative research across the ERN                                        |                                                                                                                                                                                                                     |
| Measurable Elements              |                                                                                                                    |                                                                                                                                                                                                                     |
|                                  | 5.2.1                                                                                                              | The ERN fosters collaborative instrumental efforts (multicentre trials, participation in EU projects, etc.) amongst its Members, Affiliated Partners and relevant patient, professional and research organisations. |
| 5.3                              | The ERN reinforces research and epidemiological surveillance through setting up of shared registries and databases |                                                                                                                                                                                                                     |
| Measurable Elements              |                                                                                                                    |                                                                                                                                                                                                                     |
|                                  | 5.3.1                                                                                                              | The ERN works to establish an EU wide solution for data sharing.                                                                                                                                                    |
|                                  | 5.3.2                                                                                                              | The ERN promotes the development of comprehensive registries and databases.                                                                                                                                         |

| AREA 6. EDUCATION AND TRAINING |                                                                                                                                                                                   |                                                                                                                                                                                  |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6.1                            | The ERN has identified education, training, and professional development gaps within its area of expertise and has defined and addressed priority areas for teaching and training |                                                                                                                                                                                  |
| Measurable Elements            |                                                                                                                                                                                   |                                                                                                                                                                                  |
|                                | 6.1.1                                                                                                                                                                             | The ERN has identified education, training, and professional development gaps within its area of expertise and defined priority areas for teaching and training.                 |
|                                | 6.1.2                                                                                                                                                                             | Plans have been implemented to address the priority areas for teaching and training in collaboration with Member States, scientific societies, and other partners.               |
|                                | 6.1.3                                                                                                                                                                             | The plans have been evaluated and the areas of improvement identified have been addressed in the plans for the coming years.                                                     |
|                                | 6.1.4                                                                                                                                                                             | ERN members periodically meet to review and share best practices, and discuss new evidence-based treatments, therapies, and healthcare technologies.                             |
| 6.2                            | The ERN has enhanced educational activities and training opportunities across Europe for HCPs within and outside the ERN.                                                         |                                                                                                                                                                                  |
| Measurable Elements            |                                                                                                                                                                                   |                                                                                                                                                                                  |
|                                | 6.2.1                                                                                                                                                                             | Actions oriented to improve access to the educational resources available across Europe have been carried out.                                                                   |
|                                | 6.2.2                                                                                                                                                                             | The participation of specialized HCPs from Member States with insufficient number of patients or lacking technology or expertise has been facilitated and increasingly achieved. |

| AREA 7. NETWORKING AND DISSEMINATION |                                                                                                                                                                   |                                                                                                                                                                                                                                                                             |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1                                  | The ERN has developed a robust networking system for national and international collaboration and sharing of knowledge, best practices, expertise, and resources. |                                                                                                                                                                                                                                                                             |
| Measurable Elements                  |                                                                                                                                                                   |                                                                                                                                                                                                                                                                             |
|                                      | 7.1.1                                                                                                                                                             | The ERN has enhanced the collaboration with other ERN and HCPs to exchange and disseminate knowledge, best practices, clinical expertise, or other resources.                                                                                                               |
|                                      | 7.1.2                                                                                                                                                             | The ERN has developed collaboration strategies with Affiliated Partners from Member States with an insufficient number of patients or lacking technology or expertise to develop their skills.                                                                              |
|                                      | 7.1.3                                                                                                                                                             | The ERN has developed partnerships with other stakeholders of interest, such as scientific societies, centres of expertise, diagnostic laboratories, patient organisations, social care providers, industry, affiliated research groups or national healthcare authorities. |
| 7.2                                  | The ERN has developed information and dissemination strategies regarding referrals across Member States.                                                          |                                                                                                                                                                                                                                                                             |
| Measurable Elements                  |                                                                                                                                                                   |                                                                                                                                                                                                                                                                             |
|                                      | 7.2.1                                                                                                                                                             | The ERN provides accessible information highlighting sites for cross border expert advice and patients’ referrals.                                                                                                                                                          |
| 7.3                                  | The ERN gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside the ERN.                                |                                                                                                                                                                                                                                                                             |
| Measurable Elements                  |                                                                                                                                                                   |                                                                                                                                                                                                                                                                             |
|                                      | 7.3.1                                                                                                                                                             | The ERN has defined and implemented a comprehensive communication and dissemination strategy.                                                                                                                                                                               |
|                                      | 7.3.2                                                                                                                                                             | The ERN has developed actions to align information across target groups, i.e., defining audience, message, and methods to achieve the maximum level of inclusiveness of different groups.                                                                                   |

## Operational criteria for the evaluation of HCPs

| AREA 1. PATIENT CENTRED CARE. |                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                            |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1                           | The HCP team has implemented strategies to ensure that care is patient-centred, and that patients’ rights, and preferences are respected.                                                                            |                                                                                                                                                                                                                                                                                                            |
| Measurable Elements           |                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                            |
|                               | 1.1.1                                                                                                                                                                                                                | The HCP team provides patients and/or their families with written information about the facility, the organisation, and its specific area of expertise.                                                                                                                                                    |
|                               | 1.1.2                                                                                                                                                                                                                | The HCP team gives patients and/or their families written information about their rights and responsibilities in a language they can understand                                                                                                                                                            |
| 1.2                           | The HCP team provides educational activities for patients and their families with the aim of improving knowledge of the disease and the capacity for self-management to face the different aspects of their disease. |                                                                                                                                                                                                                                                                                                            |
| Measurable Elements           |                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                            |
|                               | 1.2.1                                                                                                                                                                                                                | Patient and family educational needs are addressed in a defined process.                                                                                                                                                                                                                                   |
|                               | 1.2.2                                                                                                                                                                                                                | Education activities are recorded in the medical record.                                                                                                                                                                                                                                                   |
| 1.3                           | The HCP team provides patients with clear and transparent information about the complaints’ procedures and remedies and ways of redress available for both domestic and foreign patients.                            |                                                                                                                                                                                                                                                                                                            |
| Measurable Elements           |                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                            |
|                               | 1.3.1                                                                                                                                                                                                                | The information about complaints, violation of the rights, and concern of the care and/or safety of patients and their families is periodically analysed and integrated into a continuous quality improvement process. An annual report is made on the complaints and the improvement actions carried out. |
| 1.4                           | The HCP team regularly collects information on patient satisfaction within the ERN’s area of expertise and uses this information to make ongoing improvements.                                                       |                                                                                                                                                                                                                                                                                                            |
| Measurable Elements           |                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                            |
|                               | 1.4.1                                                                                                                                                                                                                | The HCP team routinely measures patient and family satisfaction using the ERN common tool.                                                                                                                                                                                                                 |
| 1.5                           | The HCP team obtains the patient informed consent to provide clinical treatments and procedures.                                                                                                                     |                                                                                                                                                                                                                                                                                                            |

## AREA 1. PATIENT CENTRED CARE.

### Measurable Elements

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| 1.5.1      | The Informed Consent (IC) is documented in the patient's medical record, including the risks, benefits, and alternatives of the procedure to be performed, and must be understandable to patients. |
| 1.5.2      | The document to obtain IC for research must contain information on the risks, benefits, and alternatives of the procedure to be performed, and conflict of interest (financial or not financial).  |
| 1.5.3      | The patients' medical records included in a clinical trial contains information about their participation in it.                                                                                   |
| <b>1.6</b> | <b>The HCP team maintains transparency by providing information to patients about clinical outcomes, treatment options, and quality and safety standards that are in place.</b>                    |

### Measurable Elements

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| 1.6.1      | The HCP team provides comprehensive diagnostic and treatment information.                                                                                   |
| 1.6.2      | Information is provided in the language of the different populations being served.                                                                          |
| 1.6.3      | The information necessary for the follow-up of the patient after the treatment is provided.                                                                 |
| 1.6.4      | The HCP team provides information on coordinating care with other levels of care.                                                                           |
| 1.6.5      | The information provided to the patient and the family on the follow up and coordinating care with other levels of care is included in the clinical record. |
| 1.6.6      | Unanticipated outcomes and complications are disclosed to patients and their families as established in the HCP policy/procedure.                           |
| <b>1.7</b> | <b>The HCP implements a pain identification and management protocol.</b>                                                                                    |

### Measurable Elements

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| 1.7.1      | In hospitalised patients with rare or low prevalence complex disease patients, pain is regularly identified with a standardised scale as established in the hospital's protocol. |
| <b>1.8</b> | <b>A policy is implemented to encourage patient and family involvement.</b>                                                                                                      |

### Measurable Elements

## AREA 1. PATIENT CENTRED CARE.

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|  | 1.8.1 | Professionals encourage the participation of the patient and their family, based on their interests, in the care process and in decision-making. |
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| <b>1.9</b> | <b>The HCP team collaborates and carries out activities with patient associations.</b> |  |
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### Measurable Elements

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|  | 1.9.1 | The HCP team provides information on patients' associations that can support the patient and family. |
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|  | 1.9.2 | The HCP team collaborates and carries out activities with patients' associations. |
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| AREA 2. ORGANISATION AND MANAGEMENT |                                                                                                                                                                                                                |                                                                                                                                                                                                                                                  |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1                                 | The HCP team follows policies and procedures to manage the services offered to cross-border patients, including an easy access to information regarding any tariffs that may be in place.                      |                                                                                                                                                                                                                                                  |
| Measurable Elements                 |                                                                                                                                                                                                                |                                                                                                                                                                                                                                                  |
|                                     | 2.1.1                                                                                                                                                                                                          | The HCP team establishes collaboration with affiliated centres in neighbouring countries for cross-border care or for training / dissemination of information for professionals and patients.                                                    |
|                                     | 2.1.2                                                                                                                                                                                                          | The HCP team establishes and maintains a set of policies and procedures addressing aspects for the management and health care services of cross border patients.                                                                                 |
|                                     | 2.1.3                                                                                                                                                                                                          | The HCP team shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, as well as services provided and expected benefits.                                                       |
| 2.2                                 | The HCP team implements procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients. |                                                                                                                                                                                                                                                  |
| Measurable Elements                 |                                                                                                                                                                                                                |                                                                                                                                                                                                                                                  |
|                                     | 2.2.1                                                                                                                                                                                                          | When necessary, the HCP team has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.                                                       |
|                                     | 2.2.2                                                                                                                                                                                                          | The HCP team sends to the receiving organization a written summary about the patient's clinical condition and the interventions carried out in the hospital from which he/she is referred. The process is stored in the patient’s health record. |
| 2.3                                 | The HCP team has policies and procedures implemented to communicate with clinicians post discharge, including cross border.                                                                                    |                                                                                                                                                                                                                                                  |
| Measurable Elements                 |                                                                                                                                                                                                                |                                                                                                                                                                                                                                                  |
|                                     | 2.3.1                                                                                                                                                                                                          | Discharge reports contain at a minimum: diagnoses, significant physical findings; diagnostic, surgical and medical procedures performed, medication received at discharge, and follow-up instructions.                                           |
|                                     | 2.3.2                                                                                                                                                                                                          | The HCP team provides clinicians post discharge with complete discharge summaries in English for all cross-border patients.                                                                                                                      |

| AREA 2. ORGANISATION AND MANAGEMENT |                                                                   |                                                                                                                                                                           |
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| 2.4                                 | The HCP team is integrated into national networks.                |                                                                                                                                                                           |
| Measurable Elements                 |                                                                   |                                                                                                                                                                           |
|                                     | 2.4.1                                                             | The HCP team collaborates in training or dissemination activities with centres which are not members of the ERN                                                           |
| 2.5                                 | The HCP team uses CPMS and includes all the information required. |                                                                                                                                                                           |
| Measurable Elements                 |                                                                   |                                                                                                                                                                           |
|                                     | 2.5.1                                                             | The HCP team shares patient information or participates in panels regarding complex cases through the CPMS with other members of the ERN.                                 |
|                                     | 2.5.2                                                             | The CPMS of each patient includes:<br>a) physical needs<br>b) social needs<br>c) psychological and spiritual needs<br>d) treatment and care plan<br>e) sign off completed |

| AREA 3. RESEARCH, EDUCATION AND TRAINING |                                                                                                                                                                                     |                                                                                                              |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| 3.1                                      | The HCP team participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals. |                                                                                                              |
| Measurable Elements                      |                                                                                                                                                                                     |                                                                                                              |
|                                          | 3.1.1                                                                                                                                                                               | The HCP team has a defined set of objectives for its education and training activities aligned with the ERN. |

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|                     | 3.1.2                                                                                                                            | The HCP team regularly detects the training needs of the staff members.                                                                                          |
|                     | 3.1.3                                                                                                                            | Education and training activities are delivered to providers involved in the same chain of care within and outside the HCP's facility.                           |
|                     | 3.1.4                                                                                                                            | The HCP team participates in the training activities organised by the ERN.                                                                                       |
| 3.2                 | The HCP team has the capacity to carry out research activities and demonstrated research experience in the framework of the ERN. |                                                                                                                                                                  |
| mEasurable Elements |                                                                                                                                  |                                                                                                                                                                  |
|                     | 3.2.1                                                                                                                            | The HCP team leads and/or participates in research activities and clinical trials, at both national and international level, within the ERN's area of expertise. |
|                     | 3.2.2                                                                                                                            | The HCP team ensures that records from research activities and clinical trials are safely stored.                                                                |
|                     | 3.2.3                                                                                                                            | The HCP team involves patients and / or their representatives in the most relevant aspects of the research process.                                              |
|                     | 3.2.4                                                                                                                            | The HCP team shares the results, in a timely manner, from its research activities and clinical trials through scientific publications.                           |
|                     | 3.2.5                                                                                                                            | The results are disseminated to patient associations in lay language.                                                                                            |
|                     | 3.2.6                                                                                                                            | The HCP team provides patients' information for the registries or databases promoted by the ERN.                                                                 |
|                     | 3.2.7                                                                                                                            | THE HCP team is contributing to disseminate the ERN activities.                                                                                                  |

#### AREA 4. EXCHANGE OF EXPERTISE, INFORMATION SYSTEMS, AND e-HEALTH

##### **4.1 The HCP team is able to exchange expertise with other providers and provide support to them.**

###### Measurable Elements

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| 4.1.1 | The HCP team offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment. |
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##### **4.2 The HCP team fosters the use of telemedicine and other e-health tools within and outside its facility.**

###### Measurable Elements

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| 4.2.1 | The HCP team uses telemedicine and other e-health tools.                                                                                    |
| 4.2.2 | Professional telemedicine guidelines available are used to guarantee the homogeneity of its use.                                            |
| 4.2.3 | The HCP team should identify inclusion and exclusion criteria for potential telehealth patients.                                            |
| 4.2.4 | Patients and family members who access telehealth have the right to have their privacy guaranteed.                                          |
| 4.2.5 | When surveying patient and family satisfaction, satisfaction with the services provided by telehealth should be included, when appropriate. |

##### **4.3 The HCP team codes the information and the information system is aligned with nationally and internationally recognised systems when appropriate in the framework of the ERN.**

###### Measurable Elements

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| 4.3.1 | The HCP team uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s), agreed within the ERN. |
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## AREA 5. QUALITY AND SAFETY

**5.1 The HCP team regularly monitors and improves the quality and safety of the care provided to patients with rare or low prevalence complex diseases or conditions.**

### Measurable Elements

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| 5.1.1 | The HCP team applies a strategy of quality and safety improvement, which includes specific objectives and recommended activities for the achievement of the objectives.                                                                                                                                                                                                                                   |
| 5.1.2 | The main objectives of the strategy of quality and safety improvement include:<br>a) Hand hygiene<br>b) Prevention and control of healthcare related infection<br>c) Prevention of medication errors (completed medical orders, process of administration, identified high-risk medications)<br>d) Ensure safe surgery (verification, time out and sign out)<br>e) Unequivocal identification of patients |
| 5.1.3 | The quality and safety strategies are implemented, and the results obtained are evaluated.                                                                                                                                                                                                                                                                                                                |
| 5.1.4 | There is a procedure in place to report, document, investigate, and learn from adverse events and complications.                                                                                                                                                                                                                                                                                          |
| 5.1.5 | The HCP team uses this information to make ongoing improvements.                                                                                                                                                                                                                                                                                                                                          |
| 5.1.6 | All healthcare personnel are familiar with the system for reporting safety incidents and adverse events.                                                                                                                                                                                                                                                                                                  |
| 5.1.7 | A procedure is implemented to provide information on adverse events with patient damage to patients and their families.                                                                                                                                                                                                                                                                                   |

**5.2 The HCP team adopts and uses clinical practice guidelines in their area of expertise.**

### Measurable Elements

|       |                                                                                                                                        |
|-------|----------------------------------------------------------------------------------------------------------------------------------------|
| 5.2.1 | The HCP team adopts and implements clinical practice guidelines <b>and decision-making tools</b> developed or adapted by the ERN.      |
| 5.2.2 | An annual evaluation on adequate compliance of the clinical practice guidelines is carried out using the indicators agreed in the ERN. |

| AREA 6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE. |                                                                                |                                                                                                                                                                                                     |
|-------------------------------------------------------|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6.1                                                   | The HCP team maintains its clinical competence in the ERN’s area of expertise. |                                                                                                                                                                                                     |
|                                                       | Measurable Elements                                                            |                                                                                                                                                                                                     |
|                                                       | 6.1.1                                                                          | To maintain its competency and expertise, the HCP team serves the minimum/optimal number of patients per year as defined by the ERN based on professional/technical standards or recommendations.   |
|                                                       | 6.1.2                                                                          | To maintain its competency and expertise, the HCP team serves the minimum/optimal number of procedures per year as defined by the ERN based on professional/technical standards or recommendations. |
|                                                       | 6.1.3                                                                          | The HCP team regularly collects, and monitors process and outcome indicators as established in the ERN.                                                                                             |
|                                                       | 6.1.4                                                                          | The HCP team is actively involved in the activities organised for the development of the ERN.                                                                                                       |

## AREA 7. HUMAN RESOURCES

**7.1 The HCP has a team of trained professionals with the required competencies within the ERN's area of expertise.**

### Measurable Elements

7.1.1 The HCP team identifies and documents the skills and professional qualifications required for the new staff in the multidisciplinary team performing activities critical to the quality of patient care.

7.1.2 There is a process to routinely assess staff skill to ensure adequate performance of specialised tasks.

**7.2 The HCP team delivers a comprehensive care by a multidisciplinary and specialised team.**

### Measurable Elements

7.2.1 There are regular structured meetings between multidisciplinary team members.

7.2.2 The decisions of the multidisciplinary clinical sessions on a determined patient are recorded in their medical record.