

## Istituto Ortopedico Rizoli, Italy

### 1. Respondent Profile

1.1 Please indicate the type of organisation on behalf of which you are responding to this consultation:

Academic/public health and healthcare specialised institution/organisation (e.g. Institutes and University Departments of Public Health, Quality, Healthcare, Clinical Excellence)

Please indicate level:

National level organisation

Please indicate for what the administration is responsible:

### 1.1.1. Other (please specify):

Funded in 1896, Istituto Ortopedico Rizzoli (IOR - Bologna, Italy) is the oldest and most important orthopaedic healthcare and research reference in Italy, one of the largest orthopaedic institutions in Europe and well known all over the orthopaedic scientific world. In 1981 IOR was recognized (and regularly confirmed) as a Scientific Research Hospital by the Italian Ministry of Health. All teaching of the Faculty of Medicine and Surgery of Bologna University in the field of orthopaedics is carried out at IOR. It also houses the specialization school of Orthopaedics and Traumatology and the specialization school of Physical Therapy and Rehabilitation. There is a special cooperation agreement between Rizzoli Orthopaedic Institute and Bologna University both for healthcare, research and teaching. IOR's strength lies in the close integration between healthcare (about 150,000 patients examined and over 18,000 orthopedic operations every year) and scientific research. IOR has over 340 beds. Patients come from all over Italy and abroad. Its high level of healthcare is the result of intense scientific research and the transfer of these research results into clinical practice. Besides basic orthopaedic surgery, highly specialized operations for treating musculoskeletal tumors, pediatric diseases, spine diseases, sports diseases and degenerative hip and knee joint diseases are performed. At IOR healthcare and scientific activity is performed on the basis of a departmental organization. Every department consists of the aggregation of Structures specialized in: treatment of degenerative pathologies of the hip and knee; spine pathologies, pathologies of the foot and upper limbs; sports pathologies; tumors of the musculoskeletal system; pediatric orthopaedic pathologies; and diagnosis and treatment of rare skeletal diseases. It hosts the Cell and Musculoskeletal Tissue Bank, which is the regional referral center for the collection, conservation and distribution of cells and tissues and also a Cell Factory and a validation laboratory for the preparation of cells for clinical use. In the Institute there are 9 research laboratories specialized in: musculoskeletal cell biology, biomechanics and technology innovation, immunorheumatology and tissue regeneration, movement analysis, orthopaedic pathophysiology and regenerative medicine, preclinical and surgical studies, implant infections, experimental oncology and medical technology. Research is divided into current research and finalized research (about 250 publications/year and 50 patents until 2010). The current research is programmed according to a triennial plan that follows six main thematic: 1. Oncology; 2. Reconstructive prosthetic surgery; 3. Computer-aided medicine; 4. Musculoskeletal regenerative medicine; 5. General orthopaedics and traumatology; 6. Medical orthopaedic pathology. A third new department called Rizzoli RIT-Research, Innovation & Technology: the mission of RIT is research and technological transfer of the results in the field of Science of Life and Health Technologies and includes 6 Research Structures : 4 biomedical labs and 2 bioinformatic labs. In 2011 one additional Department has been established at IOR, named Rizzoli-Sicilia and involving a joint hospital and Research Center between Rizzoli and the Sicily Region. In year 2011, two more projects have been approved and funded by the National Operating Programme (PON) for years 2007-2013, which will give rise to two new laboratories in collaboration with the University of Palermo. The two labs will develop projects on: 1. Technological platforms for tissue engineering, and, 2. Development of a novel platform for the non-invasive treatment of oncological and infectious diseases based on Focalized Ultrasounds (FUS). The instrument and facilities at IOR include: NMR-3T associated with FUS, In vivo MicroCT, 5 laboratory "biosafety" including 1 at BCL2 grade, all necessary equipment for cell culture, RT-PCR machines, Citofluorimeter and sorter, a wide array of microscopes (including inverted, fluorescence and confocal microscopes), equipment for proteomic analysis and chromatography, Flexercell apparatus for the induction of a loading pressure to cell cultures, bioreactor for perfusion-based three dimensional culture system. Furthermore, IOR includes a certified cell factory for clinical-grade culture of human cells. Furthermore, the Department Rizzoli-RIT (Research and Technology Innovation), that consists of 6 more laboratories (2 bio-informatics and 4 bio technology), is part of the Regional High Technology Network. The aim of this network is to improve interaction between industry and research so that results have an impact on the industrial world. Please see the Institute website: [www.ior.it](http://www.ior.it)

1.2 Please indicate the name of your organisation or centre:

Istituto Ortopedico Rizzoli

1.3 Please indicate the country where your organisation/centre is located/has its headquarters or main representative office in Europe:	IT
1.4 Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) and accessing country (Croatia) in which your organisation conducts business/is represented:	20
1.5 If need be, can we contact you by e-mail to obtain further information on your submission?	Yes
1.5.1 Please provide an e-mail address where we can contact you:	andrea.rizzi@ior.it
1.6 Please provide us with a contact person (incl jobtitle and daytime phone number):	Dr. Andrea Rizzi, Jobtitle: European projects office responsible - Ethical Committee secretary member Daytime 8:15-17:00 phone number: +39 0516366923
1.7 Please provide additional contact details if needed:	Dr. Luca Sangiorgi, Jobtitle: Head of medical genetics and rare orthopaedic diseases ward Daytime: 8:30-17:30 phone number: +39 0516366519 email: luca.sangiorgi@ior.it

## 2. Involvement of your organisation in the matter of centres of excellence/reference (COE) and healthcare networks in highly specialised healthcare (HSHC).

2.1 How would you describe your organisation's knowledge of CoE and HSHC?	Very high
2.1.1 Space for further comments:	Regional Orthopaedic HUB for: Oncology Spinal Surgery Peditry Prosthesis and serious infectuous bone desease Foot surgery 1 Muscoloskeletal tissue bank Genetic Nexly: shoulder and elbow
2.2. What aspects or domains related to the topic of CoE and HSHC would correspond to your organisation's key knowledge? (cross any that applies)	Highly specialised healthcare provision Management and organisational aspects of highly specialized healthcare Professional performance, clinical practice, quality and safety of specialized healthcare Assessment/evaluation/certification of clinical practice and healthcare providers
2.2.1. Space for further comments:	Plan/management of basic, clinic, in vivo and industrial research National and International Workshops, courses, seminars organisation Patients Association Orthopaedic HUB
2.3 Is highly specialised healthcare a priority in your organisation's strategies and work plans?	Very high
2.3.1 Space for further comments:	The translational research is one of the most effective actions we have at IOR, therefore the implementation of the innovation is the driver for the very high specialized healthcare

2.4. What specific field of healthcare services/specialities are most relevant for your centre/organisation's field of work?	Medical/Surgical speciality
Please specify:	Orthopedic Surgery, Peditry, Oncology, Prosthesis
2.5. Has your organisation/centre been directly involved in the design or assessment of professional standards and criteria related with highly specialised healthcare?	Frequently
2.5.1 Please describe your role in such actions/projects:	President/Member Soc.as EORS CTOS EFORT SIOT ICCB 70 Eu Projects 4 as coordinator: FP5QLGI MyoCluster; FP6LSHC Prothets; FP7ICT VPHOP and NMS Physiome 23 Patents Scientific Editor,reviewer,writer
2.6. Has your organisation been involved in projects/activities supported by the Commission in relation with HSHC or professional and technical criteria/standards in highly specialised healthcare?	Yes

2.7. Do you have concrete examples based on your own organisation's experience or could you provide us with references or links to documents related with professional criteria and standards in highly specialised healthcare/CoE or HSHC (e.g. quality criteria, guidelines, consensus documents)?

Yes

2.7.1 Space for further comments:

Certified ISO 9001/2008 Regional accreditation of healthcare Org. Accreditation of industrial research org National/Int.Guidelines as: Treatment of Osteosarcomas, Prosthesis revision, peditary, etc

2.13. What is the scope of the network?

2.14. Which kind of network?

2.14.1 Space for further comments:

2.15. Would you be interested in applying to the process to be considered Centre of Excellence of the future European Reference Network? (1 = not interested at all, 5 = very interested)

2.15.1 Space for further comments:

### 3. Proposed criteria for ERN (scope, general and specific criteria)

### 3.1 Criteria related with diseases or conditions in order to be considered under the scope of the ERN

3.1.1. Need of highly specialised healthcare 5

3.1.1.1. Complexity of the diagnosis and treatment 5

3.1.1.2. High cost of treatment and resources 5

3.1.1.3. Need of advanced/highly specialised medical equipment or infrastructures 5

3.1.2. Need of particular concentration of expertise and resources 5

3.1.2.1. Rare expertise/need of concentration of cases 5

3.1.2.2. Low prevalence/incidence/number of cases 4

3.1.2.3. Evaluated experiences of Member States 3

3.1.3. Based on high-quality, accessible and cost-effective healthcare 5

3.1.3.1. Evidence of the safety and favourable risk-benefit analysis 4

3.1.3.2. Feasibility and evidence of the value and potential positive outcome (clinical)	5
3.1.4. Do you recommend any additional criteria or option that would effectively address the issue?	No
3.1.5. Would you prioritise or suggest any concrete disease or group of diseases to be addressed by the future ERN according to the above criteria?	Yes
3.1.5.1 Explain your proposal in free text:	All Orthopedic Surgery i.e. Oncology, Spinal Surgery, Pediatrics, Hip-knee-ankle Prosthesis, Serious infectious bone disease, Foot, Rare diseases, Shoulder, Regenerative Medicine, Musculoskeletal tissue bank

### 3.2. General criteria of the centres wishing to join a European Reference Network

3.2.1. Organisation and management	4
3.2.2. Patients empowerment and centered care	5
3.2.3. Patient care, clinical tools and health technology assessment	5
3.2.4. Quality, patient safety and evaluation framework policies	5



3.2.5. Business continuity, contingency planning and response capacity	4
3.2.6. Information systems, technology and e-health tools and applications	4
3.2.7. Overall framework and capacity for research and training	5
3.2.8. Specific commitment of the management/direction of the centre/hospital to ensure a full and active participation in the ERN	4
3.2.9. Do you recommend any additional option that would effectively address the issue?	No
3.2.9.1. Space for further comments:	

### 3.3. Specific criteria regarding the areas of expertise

3.3.1. Competence, experience and good outcomes and care	5
3.3.2. Specific resources and organisation:	5
3.3.2.1. Human resources	5
3.3.2.2. Team/centre organisation	4
3.3.2.3. Structural conditions	4

3.3.2.4. Specific equipment	5
3.3.2.5. Presence and coordination with other required complementary units or services	4
3.3.3. Patient care pathways, protocols and clinical guidelines in the field of expertise	5
3.3.4. External coordination, care management and follow-up of patients	4
3.3.5. Research, training, health technology assessment in the field of expertise	5
3.3.6. Specific information systems	4
3.3.7. Do you recommend any additional criteria or option that would effectively address the issue?	Yes
3.3.7.1. Space for further comments:	The Survey is missing the questions from 2.8 to 2.15, as reported in the PDF downloaded from the Public Health site, that I consider very important Centre formally recognised as reference/excellence