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Paving the way for future pan-European Clinical Trials

Pan-European collaboration is important for many clinical trials and essential for trials that are investigating treatments for rare diseases. That was the message delivered today by the European Medical Research Councils (EMRC), the membership organisation for medical research councils across Europe based at the European Science Foundation (ESF) in Strasbourg, which is coordinating two trials in rare diseases and about to launch a review of how best to implement clinical trials that are initiated by investigators. This 'forward look', will draw upon the experiences of the two trials that are underway.

For many rare conditions, there are insufficient numbers of patients in any single country to allow meaningful clinical trials to seek better treatments. To overcome this problem the ESF programme called Pan-European Clinical Trials (ECT) has seen the successful launch of two trials into rare bone conditions, osteosarcoma and fibrous dysplasia. The two trials now underway are being coordinated through the ESF's EUROCORES scheme, which is a framework to promote and stimulate European collaborative research. While setting up these two trials, the coordinators had to overcome a number of challenges.

The EURAMOS clinical trial, which involves collaboration across 11 European countries, as well as the USA and Canada, is recruiting some 1,400 patients over the next few years to improve treatment for osteosarcoma, the most common bone cancer in children. The trial has already recruited more patients than any other osteosarcoma trial ever performed. Professor Stefan Bielack (Olgahospital, Stuttgart, Germany), the coordinator of the EURAMOS trial, said, "While sarcomas are rare, accounting for less than one per cent of all cancers, they are some of the most frequent that occur in childhood and adolescence. Treatment is complex and collaboration between many centres and different countries is crucial."

The second trial being undertaken, PROFIDYS, is designed to assess the safety, tolerability and efficacy of a class of drug called bisphosphonates in the reduction of bone pain and osteolytic lesions in patients with fibrous dysplasia of the bone, a rare congenital bone disease characterized by replacement of normal bone by fibrous-like, disorganised and fragile tissue. Five countries across Europe are involved. The coordination center of the trial is the Institut National de la Santé et de la Recherche Médicale (Inserm), which acts also as the national sponsor.

"Because this is a rare disease it does not get the interest of the big pharmaceutical companies," said Professor Philippe Orcel (Hôpital Lariboisière, Paris, France), the trial's coordinator. "This is one of the very important aspects of this kind of trial. Also because it is so rare we need a multinational effort to recruit enough patients to be able to properly evaluate treatments. For our trial we wish to include 156 patients. While this might not sound very many, it would be almost impossible to achieve this recruitment in a single European country."

Professor Orcel believes that the EMRC is well-placed to coordinate such trials across many countries. “Overall we need good coordination and more efficient evaluation and assessment of proposals. It would be better if this was done centrally rather than in each individual country.”

Dr Carole Moquin-Pattey, head of the EMRC unit, said, “The EMRC now wishes to build on these experiences to develop with the various interested parties an in-depth analysis of the current situation in Europe in an international perspective and make recommendations to allow investigator driven clinical trials to be launched as efficiently as possible for the benefit of European patients.” Over the coming year, a high-level experts group under the chairmanship of Professor Jürgen Schölmerich, Regensburg, Vice-president of the Deutsche Forschungsgemeinschaft, will produce recommendations on which are the conditions best adapted to run the investigator driven clinical trials needed for Europe and also to enable closer cooperation with other non-European countries such as the USA.

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