



International Workshop

with additional GCP Training

Clinical Trials in Neuromuscular Disorders and other rare diseases

24th June 2010 GCP Training, morning
24th – 26th June 2010 Workshop
in Freiburg, Germany

Background

One of the most common reasons for failed trials is poor protocol design. As neuromuscular disorders are very rare, clinical trials have to be multi-centre or even multinational to include enough patients. As a result, the study design for these trials is usually complex. Also, academic trials have come to face a changed regulatory environment following the implementation of the EU Clinical Trials Directive 2001/20/EC.

Therefore, the aim of this workshop is to improve the efficiency of clinical trials in neuromuscular disorders and other rare diseases by

- introducing future investigators to the fundamentals of effective clinical trial design by means of lectures
- developing study protocol drafts in small group sessions in conformance with ICH-GCP
- fostering contacts between investigators to facilitate later multinational cooperation through informal discussion sessions

Target Audience

This workshop is aimed at physicians specialising in neuromuscular disorders and other rare diseases who are interested in clinical trial work. One focus will be on study design in small numbers. Participants are asked to bring a draft study plan to provide the basis for writing a synopsis during the workshop.

About the TREAT-NMD CTCC

The Clinical Trials Coordination Centre was established in May 2007 as one activity of TREAT-NMD (www.treat-nmd.eu), a pan-European 'network of excellence' aimed at improving treatments and finding cures for patients with neuromuscular disorders. It was built up in collaboration with one of Germany's leading Departments of Neuropaediatrics and Muscle Disorders and the Clinical Trials Center (ZKS) of the University Medical Center in Freiburg, Germany. Both have longstanding experience in the field of neuromuscular disorders and in the conducting of clinical trials.

Contact for further information

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