

## Workshop Schedule

24<sup>th</sup> June 2010

08:30-12:30	ICH-GCP training	A. Zähringer
13:00-14:00	Registration	
14:00-14:15	Welcome	R. Korinthenberg
14:15-14:30	Introduction to Workshop, Presentation of Team	CTCC
14:30-15:00	Parents view on Trials, Short discussion	Frau Stumpe
15:00-15:45	Lecture: Drug Therapy in rare diseases	R. Elbers
15:45-16:00	Lecture: Project Management, general	K.Gramsch
16:00-16:45	Lecture: Project Management, in clinical trials	B. Grotejohann
16:45-17:15	Coffee break	
17:15- 18:30	Small groups: Present your study ideas	CTCC staff
18:30	Apéro	
20:00	Get together	

25<sup>th</sup> June 2010

8:30-9:15	Lecture: Regulatory aspects	S. Geismann
9:15-10:00	Lecture: Fundamentals of Biostatistics	T. Fabbro
10:00-10:30	Coffee Break	
10:30-12:00	Small groups: Develop your own Synopsis	CTCC staff
12:00-13:00	Lunch Break	
13:00-13:45	Lecture: Lessons from the DMD-CsA-Trial	J. Kirschner
13:45-14:30	Lecture Outcome measures in NMD	J. Florence
14:30-15:00	Coffee break	
15:00-15:45	Lecture : Study Design	N. Coppard
15:45-17:15	Small groups: Discussion of Outcome measures	CTCC staff + J. Florence
	Discover Freiburg	

26<sup>th</sup> June 2010

08:30-09:30	Lecture SAE Management, Safety Monitoring	G. Holder
09:30-10:00	Lecture : CRF-Design and Data Management	M. Kaufmann
10:00-11:30	Small groups: Presentation and discussion of trial plan	CTCC
11:45-12:15	Final Discussion, Evaluation	CTCC
12:15	Lunchbuffet	

## **Speakers.**

**N. Coppard** PhD

Santhera Pharmaceuticals (Switzerland) Ltd.

**Prof. R. Elbers** MD

Head of Oncology Unit, German Federal Institute for Drugs and Medical Devices (BfArM)  
member of COMP, EMEA

**T. Fabbro** PhD

Biostatistician at Clinical Trial Unit, Basel Institute of Clinical Epidemiology BICE;

**J. Florence** PT, DPT

Washington University School of Medicine, USA, Research Associate Professor

**S. Geismann**

Lawyer, Regulatory affairs manager at Treat-NMD Clinical Trial Coordination Center (CTCC);

**K. Gramsch**

Assistant Project Manager TREAT-NMD

**B. Grotejohann**

Head of Project Management at the Clinical Trials Center ZKS Freiburg;

**G. Holder** MD

Pharmacovigilance Leader, Oncology IMS Novartis Pharma AG\*

**M. Kaufmann** PhD

Biochemist. Head of Data-Management at the Clinical Trials Center ZKS Freiburg;

**J. Kirschner** MD

Neuropaediatrician at the University Children's Hospital Freiburg, Project Coordinator of  
Treat-NMD CTCC and MD-Net;

**Prof. R. Korinthenberg** MD

Director of the Department of Neuropaediatrics and Muscle Disorders at the University  
Children's Hospital Freiburg, Head of Treat-NMD CTCC and MD-NET

**E. Stumpe**

Patient Organisation Initiative 'Forschung und Therapie für SMA', mother of an SMA child  
and lawyer