Prematurely ended-statement

EudraCT number	2009-016482-28
Full title of the study	Sunphenon EGCg (Epigallocatechin-Gallat) in der Muskeldystrophie vom Typ Duchenne
Study Contact	Prof. Dr. Friedemann Paul NeuroCure Clinical Research Center NCRC AG Klinische Neuroimmunologie Charitéplatz 1, 10117 Berlin Tel. 030 450 539 705
Sponsor	Charité - Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin
Contact email address	friedemann.paul@charite.de
Product	Epigallocatechin-Gallat (EGCG) – Sunphenon EGCg
Date of the early termination of the trial	06.09.2018
Statement on discontinuation of the study	Despite considerable efforts, it is unrealistic to acquire the initially desired cases “40 Patients” within an agreed recruitment period. Duchenne's dystrophy is a rare disease, several clinical trial centers were deregistered, and recruitment capacity in the remaining active centers is limited, thus recruitment of study participants is very difficult. Furthermore, the number of cases is not based on proven statistical methods, but rather on the results of the empirical estimation. Continuation of recruitment over the year 2015 is furthermore not logical. All enrolled patients completed the study as defined in the protocol.

SYNOPSIS
entsprechend Annex 1 der *Note for guidance on structure and content of clinical study reports* (CPMP/ICH/137/95) - ICH Topic E 3

Name of Sponsor/ Representative of Sponsor:	Individual Study Table Referring to Part of the Dossier Volume: Page:	*(For National Authority Use only)*
Name of Finished Product:		
Name of Active Ingredient:		

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EudraCT-Number	2009-016482-28
Principal Investigators:	Prof. Dr. Friedemann Paul NeuroCure Clinical Research Center NCRC AG Klinische Neuroimmunologie Charitéplatz 1, 10117 Berlin
Study centre(s):	Charité – Universitätsmedizin Berlin SPZ Neuropädiatrie Campus Virchow Klinikum Augustenburger Platz 1 13353 Berlin (PD Dr. Katja von Au) DRK Kliniken Berlin Westend Klinik für Kinder- und Jugendmedizin Spandauer Damm 130, 14050 Berlin (PD Dr. Arpad von Moers) Elisabeth-Kinderkrankenhaus Abteilung Neuropädiatrie Rahel-Straus-Straße 10 26133 Oldenburg (Prof. Dr. Christoph Korenke)
Publication (reference):	
Studied period (years): (date of first enrolment) 01.12.2010 (date of last completed) 06.09.2018	Phase of development: AMG-Studie Phase II
Objectives:	
Methodology:	
Number of patients (planned and analysed): Planned 40 patients, analysed ?	
Diagnosis and main criteria for inclusion: Muskeldystrophie Typ Duchenne • Alter ab 5 Jahre	

SYNOPSIS

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• Männliche Patienten • Gehfähigkeit ohne Unterstützung von > 75 Metern Gehstrecke
Test product, dose and mode of administration, batch number: Epigallocatechin-Gallat (EGCG) – Sunphenon EGCg
Duration of treatment: 36 months per patient
Reference therapy, dose and mode of administration, batch number:
Criteria for evaluation: **Efficacy:** **Safety:**
Statistical methods:
Summary - Conclusions **Efficacy Results:** **Safety Results:** Conclusion**:**
Date of the report: