Previous Clinical Trials

SI	
SEP 2008 – JUL 2009	ALL-BFM Multicenter Study for Treatment of Children and Adolescents with Acute Lymphatic Leucemia
SI	
SEP 2008 – JUL 2009	Cooperative Weichteilsarkom Studie CWS-2002P
SI	
SEP 2008 – JUL 2009	EURO- E.W.I.N.G. 99 (EUROpean Ewing tumour working initiative of National Groups – Ewing Tumour Studies 1999)
SI	
SEP 2008 – JUL 2009	NB2004 Trial Protocol for Risk Adapted Treatment of Children with Neuroblastoma
SI	
SEP 2008 – JUL 2009	Nephroblastoma (Wilms Tumour) Clinical Trials and Study (SIOP-GPOH-2001). ClinicalTrials.gov: NCT00047138
SI	
SEP 2008 – JUL 2009	A randomized trial of the European am American Osteosarcoma Study group to optimize treatment strategies for resectable osteosarcoma based on histological response to preoperative chemotherapy
SI	
SEP 2018 – MAY 2019	Early prospective therapy trial to delay renal failure in children with Alport syndrome. EARLY-PRO-TECT-Alport. EudraCT Number: 2010-024300-10
PI	
JAN 2018 – JUL 2019	A Phase 3, openlabel, Multicenter Study of ALXN1210 in children and adolescents with Atypical-Hemolytic- Uremic syndrome. ALXN1210-aHUS-312. EudraCT Number: 2016-002499-29
PI	
JAN 2018 – AUG 2018	A single Arm study of ALXN1210 in complement inhibitor treatment naïve adult and adolescent patients with atypical haemolytic uremic syndrome (aHUS). ALXN1210-aHUS-311. EudraCT Number: 2016-002027-29
PI	
OCT 2017 – JUN 2019	A Phase III double blind , randomised study to evaluate the long-term efficacy and safety of Oxabact® in patients with primary hyperoxaluria. OC5-DB-02. EudraCT Number: 2017-000684-33
SI	
FEB 2011 – JUL 2015	MPGN-Patientenregister
PI	
FEB 2011- JUL 2015	Untersuchung von recombinant hergestellten Faktor H und CFHR 1/3
PI	
AUG 2015 – ongoing	Certain Registry
SI	
NOV 2013 – JUL 2015	An observational , non-interventional, multi-center, multi-national study of patients with atypical haemolytic syndrome (aHUS-Registry, M11-001).
SI	
FEB 2011 – JUL 2015	Register zur Erfassung der schweren Purpura Schönlein Henoch Nephritis
SI	
MAR 2011 – FEB 2012	A Phase 3, Prospective, Randomized, Double-Blind, Placebo controlled Multi-Center Study to Evaluate the Pharmacokinetics, Safety and Efficacy of Paricalcitol Capsules in Decreasing Serum Intact Parathyroid Hormone Levels in Pediatric Subjects Ages 10 to 16 years with Moderate to Severe Chronic Kidney Disease. EudraCT Number: 2013-002610-13

SI	
FEB 2012 – JUL 2015	A multicenter, randomized, open labelled study to steer immunosuppressive and antiviral therapy by measurement of virus (CMV, ADV, HSV) specific T cells in addition to determination of through levels of immunosuppressants in pediatric kidney and liver allograft recipients. An explorative study.
SI	
APR 2012 – JUL 2015	Early prospective therapy trial to delay renal failure in children with Alport syndrome. EARLY-PRO-TECT-Alport. EudraCT Number: 2010-024300-10
SI	
JUL 2019 – MAR 2020	Evaluate the Safety and Efficacy of ALLN-177 in Patients with Enteric Hyperoxaluria: A Phase III Randomized, Placebo-Controlled Study. ALLN-177-301. EudraCT Number: 2017-004352-33
PI	
JUL 2019 – MAR 2020	A phase III double-blind, randomised study to evaluate the long-term efficacy and safety of Oxabact® in patients with primary hyperoxaluria. OC5-DB-02. EudraCT Number: 2017-000684-33
PI	
JUL 2019 – MAR 2020	An Open-Label Single-Arm Treatment Extension Study to Evaluate the Long-Term Efficacy and Safety of Oxabact® for Patients with Primary Hyperoxaluria who Completed Study OC5-DB-02. OC5-OL-02 ePHEX-OLE study. EudraCT: 2018-003576-12
PI	
JUL 2019 – MAR 2020	A phase 2, open label, multi-centre study to evaluate the efficacy and safety of Oxabact® to reduce plasma oxalate in subjects with primary hyperoxaluria who are on dialysis. OC5-OL-01 Study. EudraCT Number: 2013- 004368-74
PI	
JUL 2019 – MAR 2020	Initial treatment of idiopathic nephrotic syndrome in children with mycophenolate mofetil vs. prednisone: A randomized, controlled, multicenter study (INTENT-Study). EudraCT Number: 2014-001991-76
PI	
JUL 2019 – MAR 2020	Alnylam Pharmaceuticals ILLUMINATE-A study: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study with and Extended Dosing Period to Evaluate the Efficacy and Safety of Lumasiran in Children and Adults with Primary Hyperoxaluria Type I. EudraCT Number: 2018-001981-40
PI	
JUL 2019 – MAR 2020	A Phase 2, Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Administration of ALN-GO1 in Patients with Hyperoxaluria Type I. ALN-GO1-002. EudraCT Number: 2016-003134-24.
PI	
JUL 2019 – MAR 2020	ILLUMINATE-A: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study With an Extended Dosing Period to Evaluate the Efficacy and Safety of Lumasiran in Children and Adults With Primary Hyperoxaluria Type 1. ALN-GO1-003. EudraCT Number: 2018-001981-40.
PI	
JUL 2019 – MAR 2020	ILLUMINATE-B: An Open-Label Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Lumasiran in Infants and Young Children With Primary Hyperoxaluria Type 1. ALN-GO1-004. EudraCT Number: 2018-004014-17.
PI	
JUL 2019 – MAR 2020	A Placebo-Controlled, Single-Blind, Single-Center Phase 1 Study in Normal Healthy Volunteers and Open-Label Multi-Center Study in Patients with Primary Hyperoxaluria to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Doses of DCR-PHXC Solution for Injection (subcutaneous use). DCR-PHXC-101. EudraCT Number: 2017-0035324-89.
PI	
JUL 2019 – MAR 2020	A Phase 2 Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of DCR-PHXC Solution for Injection (Subcutaneous Use) in Patients With Primary Hyperoxaluria. DCR-PHXC-201. EudraCT Number: 2018-003098-91.
PI	
NOV 2019 – MAR 2020	An Open-Label Roll-Over Study to Evaluate the Long-Term Safety and Efficacy of DCR PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria. DCR-PHXC-301. EudraCT Number: 2018-00309910.
PI	

OCT 2020 – ongoing	A phase III double-blind, randomised study to evaluate the long-term efficacy and safety of Oxabact® in patients with primary hyperoxaluria. OC5-DB-02. EudraCT Number: 2017-000684-33
PI	
OCT 2020 – ongoing	An Open-Label Single-Arm Treatment Extension Study to Evaluate the Long-Term Efficacy and Safety of Oxabact® for Patients with Primary Hyperoxaluria who Completed Study OC5-DB-02. OC5-OL-02 ePHEX-OLE study. EudraCT: 2018-003576-12
PI	
OCT 2020 – ongoing	An Open-Label Single-Arm Treatment Extension Study to Evaluate the Long-Term Efficacy and Safety of Oxabact® for Patients with Primary Hyperoxaluria who Completed Study OC5-DB-02. OC5-OL-02 ePHEX-OLE study. EudraCT: 2018-003576-12
PI	
OCT 2020 - ongoing	"An observational registry study to evaluate the use and safety of cinacalcet among paediatric patients with secondary hyperparathyroidism" - AMGEN 20180204
PI	
APR 2021 – ongoing	An Open-Label Roll-Over Study to Evaluate the Long-Term Safety and Efficacy of DCR PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria. DCR-PHXC-301. EudraCT Number: 2018-00309910.
PI	
APR 2021 – ongoing	A Phase 1 Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of a Single Dose of DCR-PHXC in Patients with Primary Hyperoxaluria. DCR-PHXC-104. EudraCT Number: 2020-000344-67
PI	
JUL 2021 – ongoing	A Phase 2 Open-Label Study to Evaluate the Safety and Efficacy of DCR PHXC in Patients With Primary Hyperoxaluria Type 1 or 2 and Severe Renal Impairment, With or Without Hemodialysis. DCR-PHXC-204.

CRA	Clinical Research Assistant
CTM	Clinical Trial Monitoring
DBD	Database Development
DM	Data Manager
DRC	Data Review Committee
DSMB	Data Safety Monitoring Board
LKP	National Coordinating Investigator, *Leiter Klinischer Prüfung* gemäß AMG
PI	Prinicipal Investigator
PM	Project Manager
PSC	Protocol Steering Committee
SAE	SAE Manager
SI	Subinvestigator