Curriculum Vitæ: Dr. med. Gesa Schalk

Qualifications as recommended in GCP guidelines

Pediatrician and Pediatric Nephrologist

Kindernierenzentrum Bonn
Im Mühlenbach 2b
53127 Bonn
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OCT 1996 – May 2003	MD
Justus-Liebig University of Gießen, Gießen, Germany	Medicine, Medical School
MAY 2003	District President of Gießen, Gießen, Germany
Justus-Liebig University of Gießen, Gießen, Germany	Medical License
OCT 2003- APR 2005	Training in Pediatrics
University Hospital of Cologne, Children`s Hospital, Cologne, Germany	Pediatrics
APR 2005 – OCT 2006	Training in Pediatrics
Sana Klinikum Remscheid, Children´s Hospital, Remscheid, Germany	Pediatrics
OCT 2006 – NOV 2007	Training in Pediatrics
University Hospital of Aachen, Children`s Hospital, Aachen, Germany	Pediatrics
SEP 2008 – JUL 2009	Training in Pediatrics
University Hospital of Cologne, Children`s Hospital, Cologne, Germany	Pediatrics
AUG 2009 – NOV 2009	Training in Pediatrics
University Hospital of Cologne, Children`s Hospital, Cologne, Germany	Pediatric Nephrology and Immunology
DEC 2009	Board Certification in Pediatrics
State Medical Council of Nordrhein, Düsseldorf, Germany	Pediatrics
DEC 2009	Pediatrician
University Hospital of Cologne, Children`s Hospital, Cologne, Germany	Pediatric Nephrology and Immunology
JUN 2011	Doctoral Level
Justus-Liebig University of Gießen, Gießen, Germany	Medicine
NOV 2012	Board Certification in Pediatric Nephrology
State Medical Council of Nordrhein, Düsseldorf, Germany	Pediatric Nephrology
NOV 2012 – JUL 2015	Pediatric Nephrologist (specialist)
University Hospital of Cologne, Children`s Hospital, Cologne, Germany	Pediatric Nephrology and Immunology
AUG 2015 – SEP 2017	Pediatric Nephrologist (consultant)
University of Zurich, Children´s Hospital, Zurich, Switzerland	Pediatric Nephrology

OCT 2017 – JUN 2019	Pediatric Nephrologist (consultant)
University of Bonn, Children´s Hospital, Bonn, Germany	Pediatric Nephrology
JUL 2019 – MAR 2020	Pediatric Nephrologist (head of nephrology department)
University of Bonn, Children´s Hospital, Bonn, Germany	Pediatric Nephrology
OCT 2019 – MAR 2020	Pediatric Nephrologist (deputy director of the general children's department)
University of Bonn, Children´s Hospital, Bonn, Germany	Pediatric Nephrology
APR 2020 –	Pediatric Nephrologist (head of institution)
Kindernierenzentrum Bonn, Bonn, Germany	Pediatric Nephrology

GCP-Experience

- 09/2008 – ongoing: Participation in various clinical trials

GCP Training

- 09.11.2022 GCP Refresher Course incl. GCP-Update Training, online, GCP-Service International
- 01.02.2021, GCP online course, NIDA Clinical Trials Network
- 05.04.2019, GCP-advanced training course, Clinical Trials Center of Düsseldorf (KKS), Düsseldorf, Germany
- 22.02.2018, Refresher Course, Training Clinical Trials Center of Bonn, Bonn, Germany
- 23.01.2013, Ethics Committee of the Medical Faculty of the University of Cologne: "Zweites Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften", Cologne, Germany
- 28/29.01.2010, Investigator Training Clinical Trials Center of Cologne, Cologne, Germany

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-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 – JUL 2021	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 – JUL 2021	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. EudraCT Number: 2018-003576-12
PI	
OCT 2020 – AUG 2024	"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 – OCT 2021	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 Dialysis. DCR-PHXC-204. EudraCT Number: 2020-002826-97.
PI	
NOV 2021 – MAR 2023	A Natural History Study of Patients with Genetically Confirmed Primary Hyperoxaluria Type 3 with a History of Stone Events. DCR-PHXC-502.
PI	
AUG 2021 – ongoing	ARegPKD Registry Registry Study on Autosomal Recessive Polycystic Kidney Disease
PI	
AUG 2021 – ongoing	Neocyst Registry Registry Study on early onset cystic kidney disease
PI	
NOV 2021 – NOV 2024	A Phase 2 Open-Label Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of Nedosiran in Pediatric Patients from Birth to 5 Years of Age with Primary Hyperoxaluria and Relatively Intact Renal Function DCR-PHXC-203. EudraCT Number: 2021-001083-16
PI	
MAR 2022 - ongoing	Phase 3, Single-arm, Open-label, Multidose, Titration, Pharmacokinetic, Pharmacodynamic, and Safety Study of Etelcalcetide in Children and Adolescents ≥ 2 to < 18 Years of age With Secondary Hyperparathyroidism and Chronic Kidney Disease Receiving Maintenance Hemodialysis AMGEN 20170724. EudraCT Number: 2018-004608-21
PI	
JUL 2022 – ongoing	EARLY_PRO-TECT_ALPORT XXL European Alport Therapy Registry
PI	
NOV 2022 - ongoing	FOrMe Registry Study on Focal Glomerulosclerosis and Minimal Change Disease

PI	
NOV 2022 - ongoing	A 6-month multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and PK/PD of an age-and body weight adjusted oral finerone regimen, in addition to an ACEI or ARB, for the treatment of children, 6 months to <18 years of age with chronic kidney disease and proteinuria. FIONA. EudraCT Number: 2021-002071-19
PI	
OCT 2023 - ongoing	A 18-month open-label, single-arm safety extension study of an age-and body weight adjusted oral finerone regimen, in addition to an ACEI or ARB, for the treatment of children and young adults from 1 to 18 years of age with chronic kidney disease and proteinuria. FIONA-OLE. EudraCT Number: 2021-002905-89
PI	
JUN 2024 - ongoing	A Phase I, open-label, uncontrolled Study to evaluate activity, safety, pharmacokinetics and pharmacodynamics of Roxodustat for the treatment of anemia in pediatric patients with chronic kidney disease. 1517-CL-1003. EudraDT Number: 2022-501980-42

Bonn, _____

LKP	National Coordinating Investigator, *Leiter Klinischer Prüfung* gemäß AMG
PI	Prinicipal Investigator
DE	Deputy
SI	Subinvestigator