

Tim Richardson

Curriculum Vitæ

Qualifications as recommended in GCP guidelines

Junior Hospital Doctor

Universitätsklinikum Köln
Kerpener Str. 62
50937 Köln, Germany

2010 – 2017 University of Cologne, Germany	Student Human medicine
2012 University of Cologne, Germany	Student Physicum
2014 – 2018 Departement for Pediatrics University of Cologne	Experimental PhD
MAY 2016 – JUL 2016 University Hospital Cologne	Practical year surgery
SEP 2016 – 2017 University Hospital Cologne	Practical year internal medicine
2017	Medical License (Approbation)
JAN 2017 – APR 2017 University Hospital Cologne	Practical year pediatrics
APR 2018 University Hospital Cologne Department of Internal Medicine I	Assistant doctor Hematology and Oncology

SCIENTIFIC AND CLINICAL QUALIFICATIONS

2014 - 2018 experimental PhD at the Children's Hospital of the University of Cologne, subject:

"Molecular effects of a protein restriction during pregnancy on the energy homeostasis of the offspring."

GCP TRAINING

01/2019 Principal Investigator Training

08/2023 Refresher EU-VO 536/2014

FURTHER RELATED TRAINING

PREVIOUS CLINICAL TRIALS

JAN 2019 SI	A Clinical Phase II, multicenter, Open-label study evaluating induction, consolidation and maintenance treatment with Isatuximab (SAR650984), Carfilzomib, Lenalidomide and Dexamethasone (I-KRd) in Primary diagnosed high-risk multiple myeloma patients Legal basis AMG · EudraCT 2016-000432-17
JUN 2020 SI	A Phase 2/3, Multicenter, randomized, Double-blind, placebo-controlled, study to evaluate the safety and efficacy of Alpha-1 Antitrypsin for the prevention of graft-versus-host disease in patients receiving hematopoietic cell transplant (MODULATE Study)
SEP 2020 SI	A Phase II/III-Study of Itacitinib or Placebo in Combination With Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease
JAN 2021 SI	A Phase 3, Multicenter, Randomized, Double-Blind Study of the Efficacy and Safety of Rezafungin for Injection Versus the Standard Antimicrobial Regimen to Prevent Invasive Fungal Diseases in Adults Undergoing Allogeneic Blood and Marrow Transplantation
MAR 2021 SI	A randomized phase III trial assessing the benefit of the addition of isatuximab to lenalidomide / bortezomib / dexamethasone (RVD) induction and lenalidomide maintenance in patients with newly diagnosed multiple myeloma)
MAR 2021 SI	A Phase 3, Multicenter, Randomized, Open-label Study to Compare the Efficacy and Safety of bb2121 Versus Standard Triplet Regimens in Subjects with Relapsed and Refractory Multiple Myeloma (RRMM)
MAY 2021 SI	Daratumumab for first line treatment of transplant-ineligible myeloma patients followed by daratumumab re-treatment at first relapse (GMMG-DADA)
SEP 2021 SI	A Phase III Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma Legal basis AMG · EudraCT 2019-001413-16
AUG 2022 SI	A Phase 1b Open-label Study to Investigate the Safety and Pharmacokinetics of Administration of Subcutaneous Blinatumomab for the Treatment of Adults with Relapsed or Refractory B cell Precursor Acute Lymphoblastic Leukemia (R/R B-ALL) Legal basis AMG · EudraCT 2019-004780-52 · NCT (clinicaltrials.gov) NCT04521231

SEP 2022 SI	<p>A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Birtamimab Plus Standard of Care vs. Placebo Plus Standard of Care in Mayo Stage IV Subjects with Light Chain (AL) Amyloidosis</p> <p>Legal basis AMG · EudraCT 2021-000037-14 · NCT (clinicaltrials.gov) NCT04973137</p>
SEP 2022 SI	<p>A Phase 2 study of PHE885, B-cell maturation Antigen (BCMA)-directed CAR-T Cells in adult participants with relapsed and refractory multiple myeloma</p> <p>Legal basis AMG · EudraCT 2021-003747-22 · NCT (clinicaltrials.gov) NCT05172596</p>
JAN 2023 SI	<p>Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG</p> <p>Legal basis AMG · EudraCT 2021-000853-17 · NCT (clinicaltrials.gov) NCT05153226</p>
SEP 2023 SI	<p>PHASE-I/II TRIAL TO ASSESS THE SAFETY AND EFFICACY OF VENETOCLAX IN ADDITION TO SEQUENTIAL CONDITIONING WITH FLUDARABINE / AMSACRINE / ARA-C (FLAMSA) + TREOSULFAN FOR ALLOGENEIC BLOOD STEM CELL TRANSPLANTATION IN PATIENTS WITH MDS, CMML OR SAML (FLAMSACLAX)</p> <p>Legal basis AMG · EudraCT 2022-002435-66 · NCT (clinicaltrials.gov) NCT05807932</p>
OCT 2023 SI	<p>A Phase 3 Randomized Study Comparing Talquetamab SC in Combination With Daratumumab SC and Pomalidomide (Tal-DP) or Talquetamab SC in Combination With Daratumumab SC (Tal-D) Versus Daratumumab SC, Pomalidomide and Dexamethasone (DPd), in Participants With Relapsed or Refractory Multiple Myeloma who Have Received at Least 1 Prior Line of Therapy</p> <p>Legal basis AMG · EudraCT 2021-000202-22 · NCT (clinicaltrials.gov) NCT05455320</p>

- CS** Central Services
- CTM** Clinical Trial Monitoring
- DBD** Database Development
- DM** Data Manager
- DepPI** Deputy of Principal Investigator
- DRC** Data Review Committee
- DSMB** Data Safety Monitoring Board
- LKP** National Coordinating Investigator
Leiter Klinischer Prüfung gemäß AMG
- MM** Medical Monitoring
- PI** Principal Investigator
- PM** Project Manager
- PSC** Protocol Steering Committee
- SAE** SAE Manager
- SC** Study Coordinator
- SI** Subinvestigator
- Stat** Statistics
- WC** Writing Committee

Place, Date

Signature