

# Prof. Dr. med. Barbara Eichhorst

## Curriculum Vitæ

Qualifications as recommended in GCP guidelines

### Senior Physician

Universitätsklinikum Köln  
Kerpener Str. 62  
50937 Köln  
Germany

<b>MAY 1997 – NOV 1998</b> University Hopsital LMU Munich Klinikum Innenstadt Department for Internal Medicine	<b>Intern</b> Hematology & Oncology
<b>NOV 1998</b> Bayrisches Sozialministerium	<b>Medical license (Approbation :15.11.1998)</b>
<b>DEC 1998 – JAN 2005</b> University Hopsital LMU Munich Klinikum Großhadern Department for Internal Medicine III	<b>Resident</b> Hematology & Oncology
<b>FEB 2005</b> University Hopsital Cologne Department for Internal Medicine I ongoing	<b>Resident</b> Hematology & Oncology

### SCIENTIFIC AND CLINICAL QUALIFICATIONS

- 12/1998 Doctoral thesis, LMU Munich
- Since 05/1997 leading member of the GCLLSG
- Since 2005 secrtary of the GCLLSG
- 01/2005 Consultancy in Internal Medicine
- 04/2007 Consultancy in Hematology and Oncology
- Since 12/2011 associate professor
- Since 01/2012 senior physician

### GCP EXPERIENCE

- Since 1997 participation and conduction of several phase I - III clinical trials.

### GCP TRAINING

- GCP training within participation of clinical trials.

### PREVIOUS CLINICAL TRIALS

<b>JAN 2003 PI, SI</b>	Phase III trial of combined immunochemotherapy with Fludarabine, Cyclophosphamide and Rituximab (FC-R) versus chemotherapy with Fludarabine and Cyclophosphamide (FC) alone in patients with previously untreated chronic lymphocytic leukaemia
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- JUN 2004** Consolidation therapy with Alemtuzumab (MabCampath®) in patients with chronic lymphocytic leukemia who are in complete or partial 2nd remission after cytoreduction with fludarabine or fludarabine plus cyclophosphamide or fludarabine plus cyclophosphamide plus rituximab or bendamustine or bendamustine plus rituximab - a phase I/II study  
**SI**
- FEB 2005** CLL2G - Cyclophosphamid, Adriamycin, Vincristin, Prednison and Rituximab (CHOP-R) with patients with Richtersyndrome  
**PI, SI**
- FEB 2005** Randomized phase III trial comparing early treatment with fludarabine, cyclophosphamide+rituximab versus deferred treatment in untreated Binet stage A patients with high risk of progression  
**DepPI**
- JUN 2005** Phase-II-trial for treatment of T-LGL-Leukaemia with Methotrexat or Fludarabin  
**SI**
- FEB 2006** Multicentre phase II trial of bendamustine in combination with rituximab for patients with previously untreated or relapsed chronic lymphocytic leukemia  
**SI**
- DEC 2006** A prospective observational descriptive study and retrospective chart review of subjects with immune (idiopathic) thrombocytopenic purpura (ITP)  
**PI**
- MAY 2008** A Phase I/IIa Study evaluating the Safety, Pharmacokinetics and Efficacy of ABT-263 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL).  
**PI, SI**
- JUN 2008** Phase III trial of combined immunochemotherapy with Fludarabine, Cyclophosphamide and Rituximab (FCR) versus Bendamustine and Rituximab (BR) alone in patients with previously untreated chronic lymphocytic leukaemia  
**LKP, PI**
- OCT 2008** A multicenter, open-label, single arm study of weekly Alvocidib in patients with previously treated B-cell chronic lymphocytic leukemia or prolymphocytic leukemia (PLL) arising from CLL  
**PI, SI**
- APR 2009** - a phase III, open label, randomized, multicenter trial of Ofatumumab added to Chlorambucil vs. Chlorambucil Monotherapy in previously untreated patients with Chronic Lymphocytic Leukemia  
**SI**
- JUL 2009 – SEP 2009** An Open-Label, Dose-Escalating Study to Investigate the Safety and Tolerability of R7159 Monotherapy in Patients With CD20+ Malignant Disease  
**SI**
- NOV 2009** Therapy optimization study in the primary therapy of early Hodgkin lymphoma: therapy stratification using FDG-PET  
**SI**
- JAN 2010** A Phase 2, Multi-Center, Randomized, Double-Blind, Parallel-Group Study Of The Safety And Efficacy Of Different Lenalidomide (Revlimid®) Dose Regimens In Subjects With Relapsed Or Refractory B-Cell Chronic Lymphocytic Leukemia  
**SI**

- MAR 2010** An open-label, multi-center, three arm randomized, phase III study to compare the efficacy and safety of RO5072759 + chlorambucil (GClb), rituximab + chlorambucil (RClb) or chlorambucil (Clb) alone in previously untreated CLL patients with comorbidities  
**SI**
- APR 2010 – MAR 2016** Phase I trial of AVD plus Lenalidomide (Revlimid®) in elderly intermediate or advanced stage Hodgkin Lymphoma patients  
**SI**
- JUN 2010** Phase II study of the combined immuno chemotherapy with Fludarabin, Mitoxantron, cyclophosphamide and Alemtuzumab (FMC Alemtuzumab) for patients with pre-treated or not pre-treated T-prolymphocytic leukaemia (T-PLL)  
**SI**
- FEB 2011** A phase I/II safety and efficacy trial of a combination of bendamustine, rituximab and lenalidomide (BRL) in patients with relapsed or refractory chronic lymphocytic leukemia  
**SI**
- FEB 2011** A Phase I, open, dose escalation trial with BI 836826 in patients with advanced Chronic Lymphocytic Leukaemia  
**SI**
- MAY 2011** An open label, multicenter study investigating the safety and efficacy of ofatumumab therapy versus physicians choice in patients with bulky fludarabine refractory chronic lymphocytic leukamia ( CLL )  
**SI**
- DEC 2011** Therapy optimization study in primary therapy of intermediate Hodgkin lymphoma: stratification of radiation therapy (involved field, involved node or none) by FDG-PET  
**SI**
- JAN 2012** A Study of RO5072759 (GA101) Plus Chemotherapy in Comparison With MabThera/Rituxan (Rituximab) Plus Chemotherapy Followed by GA101 or MabThera/Rituxan Maintenance in Patients With Untreated Advanced Indolent Non-Hodgkin's Lymphoma  
**SI**
- FEB 2012** A Phase 1b/2 Open Label Study to Evaluate the Safety and Efficacy of TRU 016 in Combination with Bendamustine vs. Bendamustine alone in Patients with Relapsed Chronic Lymphocytic Leukemia  
**SI**
- MAR 2012** A Phase I/II, Multi-centre Trial to Assess the Safety, Efficacy, and Pharmacokinetics of Eltrombopag, Administered to Thrombocytopenic Chronic Lymphocytic Leukemia Patients Prior to Alkylating Agents and/or Purine Analogue-based Therapy  
**SI**
- JUL 2012** A phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of lenalidomide (Revlimid®) as maintenance therapy for high-risk patients with chronic lymphocytic leukemia following first-line therapy  
**PI**
- SEP 2012** A phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of lenalidomide (Revlimid) as maintenance therapy for patients with B-CLL chronic lymphocytic leukemia following second-line therapy  
**SI**

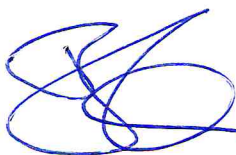
- FEB 2013** Improvement of outcome and reduction of toxicity in elderly patients with CD20+  
**SI** aggressive B-cell lymphoma by an optimised schedule of the monoclonal antibody rituximab, substitution of conventional by liposomal vincristine and FDG-PET based reduction of therapy.
- APR 2013** A Phase 1b Multi-center, Open-Label, Study to Determine the Safety and Activity of CC-292  
**DepPI, SI** in Combination with Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma
- APR 2013** An Open-label, Single arm, Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase  
**SI** Inhibitor PCI-32765 (Ibrutinib) in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma with 17p Deletion.
- APR 2013** A Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase  
**LKP, PI** Inhibitor PCI-32765 versus Chlorambucil in Patients 65 Years or Older with Treatment-naïve Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
- APR 2013** Eine offene Fortsetzungsstudie mit Patienten ab 65 Jahren mit chronischer lymphatischer  
**LKP, PI** Leukämie (CLL) oder einem kleinzelligen lymphozytischen Lymphom (SLL), die an Studie PCYC-1115-CA (PCI-32765 versus Chlorambucil) teilgenommen haben
- JUN 2013** A Phase 3, Double-Blind Extension Study Evaluating the Efficacy and Safety of Two  
**SI** Different Dose Levels of Single-Agent GS 1101 (CAL 101) as Therapy for Patients with Previously Treated Chronic Lymphocytic Leukemia
- JUN 2013** A Phase 3, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Efficacy  
**SI** and Safety of GS 1101 (CAL-101) in Combination with Rituximab for Previously Treated Chronic Lymphocytic Leukemia
- JUL 2013** A Multicenter, Open-Label, Single-Arm, Phase III, International Study Evaluating the Safety  
**PI** of Obinutuzumab Plus Chemotherapy in Subjects With First-line or Relapsed/Refractory, CD20-positive, B-cell Chronic Lymphocytic Leukemia
- AUG 2013** Registry of The German CLL Study Group: Long term follow-up of patients with CLL, B-PLL,  
**PI, SI** T-PLL, SLL, T/ NK-LGL, and Richter's transformation
- OCT 2013** A Phase 1a/1b, Multicenter, Open Label, Dose-Finding Study to Assess the Safety,  
**LKP, PI** Tolerability, Pharmacokinetics and Preliminary Efficacy of the Dual DNA-PK and TOR Kinase Inhibitor, CC-115, Administered Orally to Subjects with Advanced Solid Tumors and Hematologic Malignancies
- NOV 2013** Randomized, Double-blind, Placebo-controlled Phase 3 Study of Ibrutinib, a Bruton's  
**DepPI** Tyrosine Kinase (BTK) Inhibitor, in Combination with Bendamustine and Rituximab (BR) in Subjects With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma



- DEC 2013 DepPI** A Phase 2 Open-Label Study of the Efficacy of ABT-199 (GDC-0199) in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia Harboring the 17p Deletion
- FEB 2014 DepPI** A Phase IB, open-label study evaluating the safety and pharmacokinetics of GDC-0199 (ABT-199) in combination with Bendamustine / Rituximab (BR) in patients with relapsed / refractory or previously untreated chronic lymphocytic leukemia
- APR 2014 DepPI** A placebo-controlled, double-blind, randomized, multicenter, three arm phase III study to compare the efficacy and safety of ibrutinib vs placebo in previously untreated early Binet stage A CLL patients with risk of early disease progression
- MAY 2014 – APR 2017 SI** This is a randomized, double-blind, placebo-controlled, multicenter, phase 3 clinical trial designed to evaluate the efficacy and safety of including brentuximab vedotin (ADCETRIS) in the treatment of newly diagnosed, CD30-positive mature T-cell lymphomas
- AUG 2014 SI** A Single-arm Study to Assess the Efficacy and Safety of Oral Rigosertib in Transfusion-dependent, Low or Intermediate-1, Myelodysplastic Syndrome Patients Based on the International Prognostic Scoring System.
- AUG 2014 SI** An Open-label, Randomized Phase 3 Study of Inotuzumab Ozogamicin Compared to a Defined Investigator's Choice in Adult Patients with Relapsed or Refractory CD22-Positive Acute Lymphoblastic Leukemia (ALL)
- SEP 2014 DepPI, WC** A MULTICENTER, PHASE III, OPEN-LABEL, RANDOMIZED STUDY IN RELAPSED/REFRACTORY PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO EVALUATE THE BENEFIT OF GDC-0199 (ABT-199) PLUS RITUXIMAB COMPARED WITH BENDAMUSTINE PLUS RITUXIMAB
- DEC 2014 DepPI, PM** A prospective, open-label, multicenter, randomized Phase III-Trial to compare the efficacy and safety, of a combined Regimen of obinutuzumab and GDC-0199 versus obinutuzumab and in previously untreated patients with CLL and coexisting medical conditions.
- JAN 2015 DepPI** A prospective, open-label, multicentre phase-II trial to evaluate the efficacy and safety of a sequential regimen of bendamustine depending on tumor burden followed by GA101 and ibrutinib (BIG) followed by ibrutinib and GA101 maintenance in CLL patients
- JAN 2015 DepPI** A Phase 3 Study of IPI-145 versus Ofatumumab in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.
- JAN 2015 DepPI** A Study of IPI-145 and Ofatumumab in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Previously Enrolled in Study IPI-145-07
- APR 2015 DepPI** A prospective, multicenter, randomized phase-II trial comparing efficacy and safety of Fludarabine + Cyclophosphamide + GA101 (FCG) and Bendamustine + GA101 (BG) in patients with relapsed or refractory CLL followed by maintenance therapy with GA101 for responding patients

- APR 2015** A prospectiv, open-label, multicentre phase-II-trial to evaluate the efficacy and safety of a sequential regimen of Bendamustine depending on tumor burden followed by GA101 and ABT-199 (BAG) followed by ABT-199 and GA101 maintenance in CLL patients  
**DepPI, SC**
- MAY 2015** A Phase 2 Study of the Safety and Anti-tumor Activity of the Oral Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330) in Patients with Refractory and/or Relapsed Richter's Transformation  
**PI**
- MAY 2015** A prospective, open-label, multicentre phase-II trial to evaluate the efficacy and safety of a sequential regimen of Bendamustine depending on tumor burden followed by GA101 and CAL-101 (BCG) followed by CAL-101 and GA101 maintenance in CLL patients  
**DepPI**
- AUG 2015** A Pivotal Multicenter Trial of Moxetumomab Pasudotox in Relapsed/ Refractory Hairy Cell Leukemia  
**PI**
- FEB 2016** A prospective, open-label, multicentre phase-II trial to evaluate the efficacy and safety of a sequential regimen of bendamustine followed by ibrutinib and ofatumumab (BIO) followed by ibrutinib and ofatumumab maintenance in CLL patients  
**DepPI**
- JUL 2016** Non-Comparative, Two-Cohort, Single Arm, Open-Label, Phase 2 Study of Nivolumab (BMS-936558) in classical Hodgkin Lymphoma (cHL) Subjects after Failure of Autologous Stem Cell Transplant (ASCT)  
**SI**
- SEP 2016** Phase 1/2 Study to Determine the Safety, Pharmacokinetics, and Efficacy of Single Agent CC-122 and the Combinations of CC-122 and Ibrutinib and CC-122 and Obinutuzumab in Subjects with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma  
**DepPI**
- OCT 2016** A prospective, open-label, multicentre Phase II of ibrutinib plus Venetoclax plus obinutuzumab in physically fit (CIRS  $\leq$  6 & normal Creatinine clearance) or unfit (CIRS  $>$  or creatinine clearance  $\geq$  50ml/min) Patients with previously untreated chronic lymphocytic leukemia (CLL) with TP53 deletion (17P-) and/or Mutation  
**DepPI**
- OCT 2016** Improvement of Outcome in Elderly Patients or Patients not eligible for high-dose chemotherapy with Aggressive Non-Hodgkin Lymphoma in first Relapse or Progression by adding Nivolumab to Gemcitabine, Oxaliplatin plus Rituximab in case of CD20+ Disease  
**DepPI**
- DEC 2016** A Prospective, Randomized, Open-Label, Multicenter, Phase 2 Trial to Evaluate the Safety and Efficacy of the Combination of GS-4059 and Idelalisib with and without Obinutuzumab in Subjects with Chronic Lymphocytic Leukemia  
**LKP, PI**
- JAN 2017** A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (Rve) versus obinutuzumab (GA101) plus venetoclax (Gve) versus obinutuzumab plus ibrutinib plus venetoclax (GIVE) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without del(17p) or TP53 mutation  
**LKP, PI**

- JAN 2017** A Prospective, Randomized, Open-Label, Multicenter, Phase 2 Trial to Evaluate the Safety and Efficacy of the Combination of GS-4059 and Entospletinib with and without Obinutuzumab in Subjects with Chronic Lymphocytic Leukemia  
**LKP, PI**
- JAN 2017** A Phase II Study of Pembrolizumab (MK-3475) in Subjects with Relapsed or Refractory Primary Mediastinal Large B-cell Lymphoma (rrPMBCL) or Relapsed or Refractory Richter Syndrome (rrRS)  
**PI**
- JUL 2017** A Phase 1/2, open label, multicenter study to assess the safety and tolerability of durvalumab(anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia (MEDI4736-NHL-001)  
**DepPI**
- JUL 2017** A Randomized Multicenter Study Comparing Pixantrone + Rituximab with Gemcitabine + Rituximab in Patients with Aggressive B-cell Non-Hodgkin Lymphoma Who Have Relapsed after Therapy with CHOP-R or an Equivalent Regimen and are Ineligible for Stem Cell Transplant  
**SI**
- FEB 2018** A Phase 2 Open-label Study Investigating the Safety and Efficacy of Blinatumomab After Frontline R-Chemotherapy in Adult Subjects With Newly Diagnosed High-risk Diffuse Large B-Cell Lymphoma (DLBCL)  
**SI**
- JAN 2019** A prospective, open-label, multicenter phase-II-trial to evaluate the efficacy and safety of a sequential regimen of Bendamustin followed by GA101 (Obinutuzumab), Acalabrutinib (ACP-196) and ABT-199 (Venetoclax) in patients with relapsed/refractory CLL (CLL2-BAAG-trial of the GCLLSG)  
**DepPI**
- FEB 2019** A phase I/II safety, dose finding and feasibility trial of MB-CART2019.1 in patients with relapsed or resistant CD20 and CD19 positive B-NHL  
**DepPI**
- NOV 2019** A Phase 3, Randomized Study of Zanubrutinib (BGB-3111) Compared with Ibrutinib in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma  
**LKP, PI**
- NOV 2019** Chronic Lymphocytic Leukemia (CLL) Collaborative Study Of Real-World Evidence (CORE)  
**PI**
- FEB 2020** A prospective, open-label, multicenter phase-II trial to evaluate the efficacy and safety of zanubrutinib (BGB-3111), a BTK inhibitor, plus tislelizumab (BGB-A317), a PD1 inhibitor, for treatment of patients with Richter Transformation (CLL-RT1-trial of the GCLLSG)  
**LKP, PI**
- NOV 2020** A Multi-Center, Phase 2, Open-label, Parallel Cohort Study of Efficacy and Safety of Duvelisib in Patients with Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL)  
**DepPI**



Köln, 17.09.2021

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