



Onkologische Studien am Mitteldeutschen Krebszentrum

Rekrutierende klinische Therapiestudien an den
Universitätskliniken Jena und Leipzig

Stand: April 2022





Liebe Kolleginnen und Kollegen,

Studien sind ein unverzichtbares Instrument zur Gewinnung zuverlässiger Daten über Prävention, Diagnose, Behandlung und Prognose von Krankheiten.

Das **UniversitätsTumorCentrum Jena (UTC) am Universitätsklinikum Jena (UKJ)** und das **Universitäre Krebszentrum Leipzig (UCCL) am Universitätsklinik Leipzig (UKL)** betreuen eine Vielzahl onkologischer Studien.

Die Studienbroschüre gibt Ihnen einen Überblick über die aktuell rekrutierenden onkologischen klinischen Interventionsstudien an beiden Universitätskliniken. Sie finden die Studien nach Indikationen sortiert.

Bitte nehmen Sie gerne Kontakt zur angegebenen Studienassistenz auf, wenn Sie weitere Informationen zu einer Studie erhalten möchten.

Wir freuen uns über Ihr Interesse und helfen Ihnen gerne weiter.

Mit kollegialen Grüßen

Das Studienteam des Mitteldeutschen Krebszentrums



Mitteldeutsches Krebszentrum
<https://www.mitteldeutsches-krebszentrum.de/>





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Tagesaktuelle Übersicht

Phase I/II - Studien - Leipzig



Klinische Studien

Klinik und Poliklinik für Hämatologie,
Zelltherapie und Hämostaseologie -
Leipzig



Phase I/II - Studien - Jena



Klinische Studien

Abteilung für Hämatologie und
Internistische Onkologie - Jena



Studien durchführende Einheiten am Universitätsklinikum Jena

Klinik für Allgemein-, Viszeral- und
Gefäßchirurgie
[Prof. Dr. Utz Settmacher](#)

Klinik für Unfall-, Hand - und
Wiederherstellungschirurgie
[Prof. Dr. Dr. Gunther Hofmann](#)

Klinik für Hals-, Nasen- und
Ohrenheilkunde
[Prof. Dr. Orlando Guntinas-Lichius](#)

Klinik für Hautkrankheiten
[Dr. Steven Goetze](#)

Klinik für Innere Medizin II - Abteilung
Hämatologie und Internistische Onkologie
[Prof. Dr. Andreas Hochhaus](#)

Klinik und Poliklinik für Neurochirurgie
[Prof. Dr. Dr. Christian A. Senft](#)

Klinik und Poliklinik für Urologie
[Prof. Dr. Marc-Oliver Grimm](#)

Klinik für Kinder- und Jugendmedizin
[Prof. Dr. James Beck](#)

Klinik und Poliklinik für Frauenheilkunde
und Fortpflanzungsmedizin
[Prof. Dr. Ingo B. Runnebaum](#)

Institut für Diagnostische und
Interventionelle Radiologie (IDIR)
[Prof. Dr. Ulf Teichgräber](#)

Institut für Psychosoziale Medizin,
Psychotherapie und Psychoonkologie
(IPMPP)
[Prof. Dr. Bernhard Strauß](#)

Klinik für Strahlentherapie und
Radioonkologie
[Prof. Dr. Andrea Wittig-Sauerwein](#)

Klinik für Innere Medizin V - Pneumologie,
Allergologie
[apl. Prof. Dr. Susanne Lang](#)

Klinik für Innere Medizin IV -
Gastroenterologie, Hepatologie,
Infektiologie
[Prof. Dr. Andreas Stallmach](#)

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Studien durchführende Einheiten am Universitätsklinikum Leipzig

Klinik und Poliklinik für Frauenheilkunde
[Prof. Dr. Bahriye Aktas](#)

Bereich Hepatologie der Medizinischen Klinik II
[Prof. Dr. Thomas Berg](#)

Pädiatrische Onkologie, Hämatologie und Hämostaseologie
[Prof. Dr. Holger Christiansen](#)

Klinik und Poliklinik für Hals-, Nasen und Ohrenheilkunde
[Prof. Dr. Andreas Dietz](#)

Klinik und Poliklinik für Viszeral-, Transplantations-, Thorax- und Gefäßchirurgie
[Prof. Dr. Ines Gockel](#)

Bereich Gastroenterologie der Medizinischen Klinik II
[Prof. Dr. Albrecht Hoffmeister](#)

Klinik und Poliklinik für Strahlentherapie
[Prof. Dr. Thomas Kuhnt](#)

Universitäres Krebszentrum Leipzig (UCCL) & Medizinische Klinik und Poliklinik für Onkologie, Gastroenterologie, Hepatologie, Pneumologie und Infektiologie
[Prof. Dr. Florian Lordick](#)

Medizinische Psychologie und Medizinische Soziologie
[Prof. Dr. Anja Mehner-Theuerkauf](#)

Klinik und Poliklinik für Neurochirurgie
[Prof. Dr. Jürgen Meixensberger](#)

Medizinische Klinik und Poliklinik für Hämatologie, Zelltherapie und Hämostaseologie
[Prof. Dr. Uwe Platzbecker](#)

Klinik und Poliklinik für Dermatologie, Venerologie und Allergologie
[Prof. Dr. Jan C. Simon](#)

Klinik und Poliklinik für Urologie
[Prof. Dr. Jens-Uwe Stolzenburg](#)

Bereich Pneumologie der Medizinischen Klinik II
[Prof. Dr. Hubert Wirtz](#)

Ansprechpartner/Kontakt

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Email: studienzentrale.uccl@medizin.uni-leipzig.de



SOLIDE TUMOREN

Kopf und Hals

Primary therapy

ADRISK

Prof. Dr. med. Orlando Guntinas-Lichius
Prof. Koscienly
 03641 - 9 329354

Jena/Leipzig

Postoperative adjuvant radiochemotherapy (aRCH) with Cisplatin (C) versus aRCH with C and Pembrolizumab (P) in locally advanced head and neck squamous cell carcinoma (HNSCC); multicenter randomized Phase II study within the German interdisciplinary study group of German Cancer Society (IAG KHT); Pembro-Adjuvant-highRisk

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

DOSIS RCT

Dr. med. Franziska Nägler
Nadja Talhi
 0341 - 97 18541

Leipzig

Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

EORTC 1420

Prof. Dr. med. Orlando Guntinas-Lichius
PD Dr. med. habil. Thomas Bitter
 03641 - 9 329354

Jena/Leipzig

Phase III study assessing the “best of” radiotherapy compared to the “best of” surgery (trans-oral surgery (TOS)) in patients with T1-T2, N0-N1 oropharyngeal, supraglottic carcinoma and with T1, N0 hypopharyngeal carcinoma

Prof. Dr. med. Thomas Kuhnt
Nadja Talhi
 0341 - 97 18541

NadiHN

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig

An Open Label, Randomized Phase 2 Clinical Trial of Nivolumab investigating Efficacy and safety of Nivolumab given once prior to, concurrent to the radiotherapy (RT) and as maintenance therapy over 12 months in patients with advanced resectable HNSCC after surgery (NadiHN)

PATHOS

Prof. Dr. Susanne Wiegand
Kathrin Vogel
 0341 - 97 21702

Leipzig

A Phase III trial of risk-stratified, reduced intensity, adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer

1st line

ACT16903 THOR-707

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig

A Phase 2 non-randomized, open-label, multi-cohort, multicenter study assessing the clinical benefit of SAR 444245 (THOR-707) combined with other anticancer therapies for the treatment of participants with head and neck squamous cell carcinoma (HNSCC)

BNT 113-01

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig

An open label, Phase II randomized trial of BNT 113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable, recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) which is positive for human papilloma virus 16 (HPV 16+) and expresses PD-L1



Debio1143 **Jena/Leipzig** A randomized, double-blind placebo-controlled, Phase 3 study of Debio 1143 in combination with platinum-based chemotherapy and standard fractionation intensitymodulated radiotherapy in patients with locally advanced squamous cell carcinoma of the head and neck, suitable for definitive chemoradiotherapy (TrilyX)

Prof. Dr. med. Thomas Kuhnt
Nadja Tahlí
0341 - 97 18541

FOCUS **Leipzig** Phase 2 multicenter study investigating the tolerability and efficacy of UV1 vaccine in patients with recurrent or metastatic PD-L1 positive (CPS>_1) head and neck squamous cell carcinoma planned for first-line treatment with pembrolizumab

ISA 101b **Leipzig** A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Cemiplimab Versus the Combination of Cemiplimab With ISA101b in the Treatment of Subjects With HPV16-Positive Oropharyngeal Cancer (OPC)

KO-TIP **Leipzig** The AIM-HN and SEQ-HN Study: A 2 Cohort, Non-comparative, Pivotal Study Evaluating the Efficacy of Tipifarnib in Patients with Head and Neck Squamous Cell Carcinoma (HNSCC) with HRAS Mutations (AIM-HN) and the Impact of HRAS Mutations on Response to First Line Systemic Therapies for HNSCC (SEQ-HN)

LEAP-010 **Leipzig** A phase 3, randomized, placebo-controlled, double-blind clinical study of pembrolizumab (MK3475) with or without lenvatinib (E7080/MK7902) to evaluate the safety and efficacy of pembrolizumab and lenvatinib as 1L intervention in a PD-L1 selected population of participants with recurrent or metastatic head and neck squamous cell carcinoma (R/TM HNSCC) (LEAP-010)

2nd line

ACT16903 THOR-707 **Leipzig** A Phase 2 non-randomized, open-label, multi-cohort, multicenter study assessing the clinical benefit of SAR 444245 (THOR-707) combined with other anticancer therapies for the treatment of participants with head and neck squamous cell carcinoma (HNSCC)

BURAN **Jena** The BURAN Study of Buparlisib (AN2025) In Combination with Paclitaxel Compared to Paclitaxel Alone, in Patients with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

FOCUS **Leipzig** Phase 2 multicenter study investigating the tolerability and efficacy of UV1 vaccine in patients with recurrent or metastatic PD-L1 positive (CPS>_1) head and neck squamous cell carcinoma planned for first-line treatment with pembrolizumab

**Interlink-1**

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig A Phase 3 Randomized, Double-blind, Multicenter, Global Study of Monalizumab or Placebo in Combination with Cetuximab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck Previously Treated With an Immune Checkpoint Inhibitor.

ISA 101b

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Cemiplimab Versus the Combination of Cemiplimab With ISA101b in the Treatment of Subjects With HPV16-Positive Oropharyngeal Cancer (OPC)

≥3rd line**ISA 101b**

Prof. Dr. med. Andreas Dietz
Kathrin Vogel
 0341 - 97 21702

Leipzig A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Cemiplimab Versus the Combination of Cemiplimab With ISA101b in the Treatment of Subjects With HPV16-Positive Oropharyngeal Cancer (OPC)

Oberer Gastrointestinaltrakt

Primary therapy**CARDIA-TRIAL**

Prof. Dr. med. Ines Gockel
Nicole Kreuser
 0341 - 97 12590

Leipzig Surgery for adenocarcinomas of the gastroesophageal junction (GEJ) type II: Thoraehoracic esophagectomy vs. transhiatal extended gastrectomy (CARDIA-TRIAL)722

HSI-Studie

Prof. Dr. med. Ines Gockel
Nicole Kreuser
 0341 - 97 12590

Leipzig Vaskuläre Grenzzonendefinition mittels intraoperativem Hyperspektral-Imaging (HIS) bei Resektionen und Rekonstruktionen wegen gut- und bösartiger Erkrankungen des Ösophagus, Magens, Pankreas, Dünndarms und Rektums zur Optimierung von Heilungs-relevanten Parametern intratestinaler Anasomosen

Matterhorn

Dr. med. Udo Lindig
Diana Kathe
 03641 - 9 39 66 65

Jena A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients with Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC)

RACE/AIO-STO-0118

Dr. med. Udo Lindig
Diana Kathe
 03641 - 9 39 66 65

Jena/Leipzig Neoadjuvant Radiochemotherapy versus Chemotherapy for Patients with Locally Advanced, Potentially Resectable Adenocarcinoma of the Gastroesophageal Junction (GEJ)

Dr. med. Gertraud Stocker

Dominika Jahr
 0341 - 97 12570

SKYSCRAPER-07

Prof. Dr. med. Florian Lordick
Sophia Schmidt
 0341 - 97 12570

Leipzig A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab With or Without Tiragolumab (Anti-TIGIT Antibody) in Patients With Unresectable Esophageal Squamous Cell Carcinoma Whose Cancers Have Not Progressed Following Definitive Concurrent Chemoradiotherapy



VESTIGE/EORTC-1707-GITCG Leipzig Adjuvant immunotherapy in patients with resected gastric cancer following preoperative chemotherapy with high risk for recurrence (N+ and/or R1): an open label randomized controlled phase-2-study (VESTIGE)

Prof. Dr. med. Florian Lordick
Dominika Jahr
 0341 - 97 12570

1st line

Destiny 03 Leipzig Phase 1/2b Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (DS-8201a) Monotherapy and combinations in Adult Subjects with HER2 Overexpressing Gastric Cancer

Prof. Dr. med. Florian Lordick
Sophia Schmidt
 0341 - 97 12570

LEAP-015 Leipzig A Phase 3, Randomized Study to Evaluate the Efficacy and Safety of Pembrolizumab (MK-3475) plus Lenvatinib (E7080/MK-7902) plus Chemotherapy Compared with Standard of Care Therapy as First-line Intervention in Participants with Advanced/Metastatic HER2 Negative Gastric/Gastroesophageal Junction Adenocarcinoma (LEAP-015)

Prof. Dr. med. Florian Lordick
Claudia Schmidtchen
 0341 - 97 21242

2nd line

RAMIRIS Jena/Leipzig Ramucirumab plus Irinotecan / Leucovorin / 5-FU versus Ramucirumab plus Paclitaxel in patients with advanced or metastatic adenocarcinoma of the stomach or gastroesophageal junction, who failed one prior line of palliative chemotherapy - The Phase II/III RAMIRIS STUDY

Dr. med. Udo Lindig
Maria Gerth
 03641 - 9 396671

Dr. med. Gertraud Stocker
Sophia Schmidt
 0341 - 97 12570

TaLiOs Leipzig A 3-Arm, Randomized, Blinded, Active-Controlled, Phase II Study of RO7121661, a PD1-TIM3 Bispecific Antibody and RO7247669, a PD1-LAG3 Bispecific Antibody, Compared With Nivolumab in Participants With Advanced or Metastatic Squamous Cell Carcinoma of the Esophagus

Prof. Dr. med. Florian Lordick
Dominika Jahr
 0341 - 97 12570

≥3rd line

AMG199 Leipzig A Global Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of the Half-life Extended Bispecific T-cell Engager AMG 199 in Subjects with MUC17-Positive Gastric and Gastroesophageal Junction Cancer

Prof. Dr. med. Florian Lordick
Sophia Schmidt
 0341 - 97 12570



Darm

Primary therapy

ACO/ARO/AIO-18.2

Prof. Dr. med. Ulrich Hacker
Claudia Schmidtchen
 0341 - 97 21242

Leipzig Preoperative FOLFOX versus postoperative risk-adapted chemotherapy in patients with locally advanced rectal cancer and low risk for local failure: A randomized phase III trial of the German Rectal Cancer Study Group

BNT122-01

Prof. Dr. med. Ulrich Hacker
Claudia Lemke
 0341 - 97 12604

Leipzig A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II' (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection

CIRCULATE

Dr. med. Udo Lindig
Maria Gerth
 03641 - 9 396671

Jena/Leipzig Circulating tumour DNA based decision for adjuvant treatment in colon cancer stage II evaluation (CIRCULATE)

Prof. Dr. med. Ines Gockel

Nicole Kreuser
 0341 - 97 12590

CRBP-TS-Studie

Prof. Dr. med. Ines Gockel
Nicole Kreuser
 0341 - 97 12590

Leipzig Evaluation eines heimbasierten Trainings- und Versorgungsprogramms zur physischen und psychischen Stabilisierung bei kolorektal-, Brust- und Prostatakarzinom - Telemonitoring und Selfmanagement (CRB-TS)

FIRE-9

Dr. med. Udo Lindig
Diana Kathe
 03641 - 9 396665

Jena/Leipzig Prospective, randomized, open, multicenter Phase III trial to investigate the efficacy of active post-resection/ablation therapy in patients with metastatic colorectal cancer

Prof. Dr. med. Ulrich Hacker

Dominika Jahr
 0341 - 97 12570

HSI-Studie

Prof. Dr. med. Ines Gockel
Nicole Kreuser
 0341 - 97 12590

Leipzig Vaskuläre Grenzzonendefinition mittels intraoperativem Hyperspektral-Imaging (HSI) bei Resektionen und Rekonstruktionen wegen gut- und bösartiger Erkrankungen des Ösophagus, Magens, Pankreas, Dünndarms und Dickdarms und Rektums zur Optimierung von Heilungs-relevanten Parametern intratestinaler Anasomosen

Liver-T(wo)-Heal

apl. Prof. Dr. med. Falk Rauchfuß
Ulrike McCaulley
 03641 - 9 322694

Jena Lebertransplantation mit Lebendspende für Patienten mit nicht resektablen isolierten Lebermetastasen kolorektaler Karzinome als Zweischritt-Transplantation

RADIANCE

Prof. Dr. med. Thomas Kuhnt
Nadja Talhi
 0341 - 97 18541

Leipzig Radiochemotherapy +/-Durvalumab for locally-advanced Anal CarcinomaA multicenter,randomized,phase II trial of the German Anal Cancer Study Group

**1st line**

AIO 18.1 Prof. Dr. med. Thomas Kuhnt Nadja Talhi 0341 - 97 18541	Leipzig Short-course radiotherapy versus chemoradiotherapy, followed by consolidation chemotherapy, and selective organ preservation for MRI-defined intermediate and high-risk rectal cancer patients A randomized phase III trial of the German Rectal Cancer Study Group
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FIRE-4 Dr. med. Udo Lindig Diana Kathe 03641 - 9 396665	Jena Randomised study of the efficacy of cetuximab rechallenge in patients with metastatic colorectal cancer (RAS wild-type) responding to first-line treatment with FOLFIRI plus cetuximab
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FIRE-9 Dr. med. Udo Lindig Diana Kathe 03641 - 9 396665	Jena/ Leipzig Prospective, randomized, open, multicenter Phase III trial to investigate the efficacy of active post-resection/ablation therapy in patients with metastatic colorectal cancer
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Prof. Dr. med. Ulrich Hacker Dominika Jahr 0341 - 97 12570
--

2nd line

FIRE-4 Dr. med. Udo Lindig Diana Kathe 03641 - 9 396665	Jena Randomised study of the efficacy of cetuximab rechallenge in patients with metastatic colorectal cancer (RAS wild-type) responding to first-line treatment with FOLFIRI plus cetuximab
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RAMTAS Prof. Dr. med. Albrecht Hoffmeister Yvonne Kurth 0341 - 97 12226	Leipzig A Phase III Study of RAMucirumab in Combination with TAS102 vs. TAS102 Monotherapy in Chemotherapy Refractory Metastatic Colorectal Cancer Patients
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Leber / Gallenblase**Primary therapy**

ACTICCA-1 Dr. med. Udo Lindig Diana Kathe 03641 - 9 396665	Jena Adjuvant chemotherapy with gemcitabine and cisplatin compared to observation after curative intent resection of cholangiocarcinoma and muscle invasive gallbladder carcinoma (ACTICCA-1 trial)
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EnGraft apl. Prof. Dr. med. Falk Rauchfuß Ulrike McCaulley 03641 - 9 322694	Jena A study to compare the bioavailability and practicability of two immunosuppressive drugs (Envarsus® and Advagraf®) containing the same active substance used to prevent graft rejection in patients who have received a liver transplant for the first time.
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Product II apl. Prof. Dr. med. Falk Rauchfuß Ulrike McCaulley 03641 - 9 322694	Jena Microscopic Tumor Clearance after Liver Transplantation
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1st line

ImmuWhy

Dr. med. Udo Lindig
Maria Gerth
 03641 - 9 396671

Jena A phase II study of immunotherapy with durvalumab (MEDI4736) or durvalumab and tremelimumab, both combined with Y-90 SIRT therapy in patients with advanced stage intrahepatic biliary tract cancer (BTC) scheduled to receive Y-90 SIRT therapy as standard of care

Immuwin

Dr. med. Udo Lindig
Maria Gerth
 03641 - 9 396671

Jena A Phase II study of immunotherapy with durvalumab (MEDI4736) and tremelimumab in combination with either Y-90 SIRT or TACE for intermediate stage HCC with pick-the-winner design - IMMU-WIN

PCIA 203/18

Prof. Dr. med. Albrecht Hoffmeister
Diane Backsmann
 0341 - 97 24831

Leipzig A Multi-Centre, Randomised, Open-Label, Phase 2 Study to Assess the Safety, Tolerability and Efficacy of Fimraporfin-Induced Photochemical Internalisation of Gemcitabine Complemented by Gemcitabine/Cisplatin Chemotherapy Versus Gemcitabine/Cisplatin Alone in Patients With Inoperable Cholangiocarcinoma

2nd line

CaboRISE

PD Dr. med. Florian van Bömmel
Diane Backsmann
 0341 - 97 24831

Leipzig CaboRISE-A phase II study evaluating reduced starting dose and dose escalation of cabozantinib as second-line therapy for advanced HCC in patients with compensated liver cirrhosis

CaPture

PD Dr. med. Florian van Bömmel
Diane Backsmann
 0341 - 97 24831

Leipzig Cabozantinib treatment in a phase II study for patients with hepatocellular carcinoma (HCC) refractory to PD-1 inhibitors

ImmuWhy

Dr. med. Udo Lindig
Maria Gerth
 03641 - 9 396671

Jena A phase II study of immunotherapy with durvalumab (MEDI4736) or durvalumab and tremelimumab, both combined with Y-90 SIRT therapy in patients with advanced stage intrahepatic biliary tract cancer (BTC) scheduled to receive Y-90 SIRT therapy as standard of care

MK-7902 PN 005-00

apl. Prof. Dr. med. Thomas Ernst
Marina Liebing
 03641 - 9 396675

Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors

SOLARIS

Dr. med. Udo Lindig
Diana Kathe
 03641 - 9 396665

Jena SOLARIS – A phase-II open-label Study of pembrolizumab and Lenvatinib in patients with Advanced stage hepatocellular carcinoma who are Refractory to atezolizumab and bevacizumab/IO-based therapy

≥3rd line

MK-7902 PN 005-00

apl. Prof. Dr. med. Thomas Ernst
Marina Liebing
 03641 - 9 396675

Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors



Lunge

Primary therapy

ANAM-17-21

Prof. Dr. med. Hubert Wirtz
Patricia Berger
 0341 - 97 12674

Leipzig A phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Anamorelin HCL for the treatment of malignancy associated weight loss and anorexia in adult patients with advanced non-small cell lung cancer (NSCLC).

DOSIS RCT

Dr. med. Franziska Nägler
Nadja Talhi
 0341 - 97 18541

Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful Spinal Metastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

KEYNOTE-671

Prof. Dr. med. Hubert Wirtz
Patricia Berger
 0341 - 97 12674

Leipzig Phase III, Randomized, Double-blind Trial of Platinum Doublet Chemotherapy +/- Pembrolizumab (MK-3475) as Neoadjuvant/Adjuvant Therapy for Participants with Resectable Stage II, IIIA, and Resectable IIIB (T3-4N2) Non-small Cell Lung Cancer (NSCLC) (KEYNOTE-671)

MK7339

Dr. med. Tobias Rachow
Marina Liebing
 03641 - 9 396675

Jena Study of Pembrolizumab With Concurrent Chemoradiation Therapy Followed by Pembrolizumab With or Without Olaparib in Stage III Non-Small Cell Lung Cancer (NSCLC) (MK-7339-012/ KEYLYNK-012)

1st line

ABP

Dr. med. Tobias Rachow
Diana Kathe
 03641 - 9 396665

Jena/Leipzig Advancing Brigatinib Properties in anaplastic lymphoma kinase positive non-small cell lung cancer (ALK+ NSCLC) patients by deep phenotyping.

Prof. Dr. med. Hubert Wirtz
Patricia Berger
 0341 - 97 12674

GSK 213400 ZEAL-1

Dr. med. Tobias Rachow
Marina Liebing
 03641 - 9 396675

Jena Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as Maintenance Therapy in Participants Whose Disease has Remained Stable or Responded to First-Line Platinum-Based Chemotherapy with Pembrolizumab for Stage IIIB or IV Non-Small Cell Lung Cancer (213400)

Luminance

apl. Prof. Dr. Susanne Lang
Marina Liebing
 03641 - 9 396675

Jena A Phase IIIb, Single-arm, Multi-center, International Study of Durvalumab in Combination with Platinum and Etoposide for the First Line Treatment of Patients with Extensive-stage Small Cell Lung Cancer (LUMINANCE)

MK-7339-012

Dr. med. Tobias Rachow
Marina Liebing
 03641 - 9 396675

Jena A Phase 3 Study of Pembrolizumab (MK-3475) in Combination with Concurrent Chemoradiation Therapy Followed by Pembrolizumab with or without Olaparib Compared with Concurrent Chemoradiation Therapy Followed by Durvalumab in Participants with Unresectable, Locally Advanced, Stage III Non-Small Cell Lung Cancer (NSCLC)



2nd line

Krystal 12

apl. Prof. Dr. Susanne Lang
Marina Liebing
 03641 - 9 396675

Jena A Randomized Phase 3 Study of MRTX849 versus Docetaxel in Patients with Previously Treated Non-Small Cell Lung Cancer with KRAS G12C Mutation

VS-6766-202 Verastem

Prof. Dr. med. Hubert Wirtz
Patricia Berger
 0341 - 97 12674

Leipzig A Phase 2 Study of VS-6766-202 (Dual RAF/MEK Inhibitor) as a Single Agent and In Combination with Defactinib (FAK Inhibitor) in Recurrent KRAS-Mutant (KRAS-MT) Non-Small Cell Lung Cancer (NSCLC)

≥3rd line

VS-6766-202 Verastem

Prof. Dr. med. Hubert Wirtz
Patricia Berger
 0341 - 97 12674

Leipzig A Phase 2 Study of VS-6766-202 (Dual RAF/MEK Inhibitor) as a Single Agent and In Combination with Defactinib (FAK Inhibitor) in Recurrent KRAS-Mutant (KRAS-MT) Non-Small Cell Lung Cancer (NSCLC)

Knochen, Gelenkknorpel, Binde- und Weichteilgewebe

ValiScreenPsyDistress

PD Dr. med. Georg Osterhoff
Christian Lycke
 0341 - 97 17300

Leipzig Validation of a screening tool for psychological distress in patients with musculoskeletal tumors.

Primary therapy

DOSIS RCT

Dr. med. Franziska Nägler
Nadja Talhi
 0341 - 97 18541

Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful Spinal Metastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

TEAM HYPER-VASC

Univ.-Prof. Dr. med. Dr. rer. nat.
Gunther Hofmann
Dr. med. Matthias Vogt
 03641 - 9322878

Jena Study to evaluate the effect of arterial embolization prior to surgery on intraoperative blood loss during resection of hypervascularized soft tissue sarcoma

Haut

Primary therapy

NivoMela

Prof. Dr. med. Jan C. Simon
Johanna Wohlrab
 0341 - 97 18600

Leipzig Adjuvant nivolumab treatment in stage II high-risk melanoma - A randomized, controlled, phase III trial with biomarker-based risk stratification

**Phlogen**

Prof. Dr. med. Jan C. Simon
Silke Weidauer-Zuniga
 0341 - 97 18750

Leipzig A pivotal Phase III, open-label, randomized, controlled multi-center study of the efficacy of L19IL2/L19TNF neoadjuvant intratumoral treatment followed by surgery versus surgery alone in clinical stage III B/C melanoma patients.

PIVOT

Prof. Dr. med. Jan C. Simon
PD Dr. med. Mirjana Ziemer
 0341 - 97 18371

Leipzig A Phase 3, Randomized, Open-label Study to Compare Adjuvant Immunotherapy of Bempegaldesleukin Combined with Nivolumab Versus Nivolumab After Complete Resection of Melanoma in Patients at High Risk for Recurrence (PIVOT-12)

1st line**V937**

Prof. Dr. med. Jan C. Simon
Anja Zeuner
 0341 - 97 18371

Leipzig Phase 2, Randomized Clinical Study of Intravenous or Intratumoral Administration of V937 in Combination with Pembrolizumab (MK-3475) Versus Pembrolizumab Alone in Participants with Advanced/Metastatic Melanoma

CERPASS

Prof. Dr. med. Jan C. Simon
Christin Felkel
 0341 97 18380

Leipzig A Randomized, Controlled, Open-label, Phase 2 Study of Cemiplimab as a Single Agent and in Combination with RP1 in Patients with Advanced Cutaneous Squamous Cell Carcinoma

2nd line**MERKLIN 2**

Prof. Dr. med. Jan C. Simon
Silke Weidauer-Zuniga
 0341 - 97 18750

Leipzig A phase II, open label study to investigate the efficacy and safety of domatinostat in combination with avelumab in patients with advanced unresectable/metastatic Merkel Cell Carcinoma progressing on anti-PD-(L)1 antibody therapy - the MERKLIN 2 study

BNT111-01

Prof. Dr. med. Jan C. Simon
PD Dr. med. Mirjana Ziemer
 0341 - 97 18371

Leipzig Open-label, randomized Phase II trial with BNT111 and cemiplimab in combination or as single agents in patients with anti-PD-1-refractory/relapsed, unresectable Stage III or IV melanoma

Andere bösartige Neoplasien der Haut**2nd line****InflaRx**

Prof. Dr. med. Jan C. Simon
PD Dr. med. Mirjana Ziemer
 0341 - 97 18371

Leipzig open label, multicenter Phase II study of the C5A-Antibody IFX-1 alone or IFX-1 + pembrolizumab in patients with PD-1- or PD-L1-resistant / refractory locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC)



Brust / DCIS

Primary therapy

ADAPTcycle	Jena/Leipzig	Adjuvant Dynamic marker - Adjusted Personalized Therapy comparing endocrine therapy plus ribociclib versus chemotherapy in intermediate risk, HR+/HER2- early breast cancer (ADAPTcycle)
Prof. Dr. med. Ingo Runnebaum Beate Ludwig 03641 - 9 329156		

Prof. Dr. med. Bahriye Aktas Iris Eberhardt 0341 - 97 23937

Astefania Prof. Dr. med. Bahriye Aktas Iris Eberhardt 0341 - 97 23937	Leipzig	A Phase III, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of adjuvant ATEZOLIZUMAB or Placebo and TRASTUZUMA EMTANSINE for HER2-positive breast cancer at high risk or recurrence following pre-operative therapy
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CETC 002 Dr. med. Matthias Mäurer Andrea Jende 03641 - 9 328487	Jena	Assoziation der adjuvanten Strahlentherapie des nicht metastasierten Mammakarzinoms mit Immunmodulation und Phänotyp zirkulierender Tumorzellen in Abhängigkeit des Patientinnenalters
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Checkmate 7FL Prof. Dr. med. Bahriye Aktas Iris Eberhardt 0341 - 97 23937	Leipzig	Randomized, Multicenter, Double-blind, Placebo-controlled Phase 3 Study of Nivolumab Versus Placebo in Combination With Neoadjuvant Chemotherapy and Adjuvant Endocrine Therapy in Patients With High-risk, Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Primary Breast Cancer (CheckMate 7FL: CHECKpoint pathway and nivolumab clinical Trial Evaluation 7FL)
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CRBP-TS-Studie Prof. Dr. med. Ines Gockel Nicole Kreuser 0341 - 97 12590	Leipzig	Evaluation eines heimbasierten Trainings- und Versorgungsprogramms zur physischen und psychischen Stabilisierung bei kolorektal-, Brust- und Prostatakarzinom - Telemonitoring und Selfmanagement (CRB-TS)
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DOSIS RCT Dr. med. Franziska Nägler Nadja Talhi 0341 - 97 18541	Leipzig	Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)
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IY3-MC-JPCW eMonarch HER Prof. Dr. med. Bahriye Aktas Iris Eberhardt 0341 - 97 23937	Leipzig	A Phase III, randomized, double-blind, placebo-controlled Phase III Study of Abemaciclib plus standard adjuvant endocrine therapy in participants with high-risk, Node-positive, HR+, HER2+ early breast cancer who have completed adjuvant HER2-targeted therapy
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1st line

EPIK-B3 Dr. med. Dirk Forstmeyer Claudia Schmidtchen 0341 - 97 21242	Leipzig	EPIK-B3: A Phase III, multicenter, randomized, doubleblind, placebo-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with nabpaclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation
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**INAVO120**

Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig A Phase III randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of GDC-0077 plus Palbociclib and Fulvestrant versus Placebo plus Palbociclib and Fulvestrant in patients with PIK3CA mutant , hormone receptor positive, HER2-negative locally advanced or metastatic breast cancer

SERENA6

Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig A Phase III, double-blind, randomized study to assess switching to AZD 9833 (a next generation, oral SERD) + CDK4/6 inhibitor (Palbociclib or Abemaciclib) vs. continuing Aromatase inhibitor (Letrozole or Anastrozole) + CDK4/6 inhibitor in HR+/ HER2-MBC patients with detectable ESR1 mutation without disease progression during 1l-treatment with Aromatase inhibitor + CDK4/6 inhibitor A ctDNA guides early switch study

2nd line**EPIK-B3**

Dr. med. Dirk Forstmeyer
Claudia Schmidtchen
 0341 - 97 21242

Leipzig EPIK-B3: A Phase III, multicenter, randomized, doubleblind, placebo-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with nabpaclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation

MK-7902 PN 005-00

apl. Prof. Dr. med. Thomas Ernst
Marina Liebing
 03641 - 9 396675

Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors

OLIGOMA

Dr. med. Franziska Näßler
Nadja Talhi
 0341 - 97 18541

Leipzig Effectiveness and tolerability of metastases-directed radiotherapy in addition to standard systemic therapy in patients with oligometastatic breast cancer: A randomized controlled multinational and multicenter clinical trial

≥3rd line**SERENA6**

Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig A Phase III, double-blind, randomized study to assess switching to AZD 9833 (a next generation, oral SERD) + CDK4/6 inhibitor (Palbociclib or Abemaciclib) vs. continuing Aromatase inhibitor (Letrozole or Anastrozole) + CDK4/6 inhibitor in HR+/ HER2-MBC patients with detectable ESR1 mutation without disease progression during 1l-treatment with Aromatase inhibitor + CDK4/6 inhibitor A ctDNA guides early switch study



Vulva

Primary therapy

ELEVA

Prof. Dr. med. Ingo Runnebaum
Beate Ludwig
 03641 - 9 329156

Jena Prospektive Erhebung der klinischen Wirkung und Symptomkontrolle durch Elektrochemotherapie des inoperablen fortgeschrittenen Vulvakarzinoms

Vulvafeldresektion

Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig Vulvafeldresektion und anatomische Rekonstruktion: Neues operatives Konzept für die Lokalbehandlung des Vulvakarzinoms

Zervix

Primary therapy

Neue Tumoroperation

Zervixkarzinom
Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig Neue Tumoroperationen auf der Grundlage der ontogenetischen Anatomie für die Behandlung des Zervix- und Vaginalkarzinoms: TMMR, KMMR, EMMR, LEER und tLNE

1st line
KEYNOTE-A18

Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig A randomized, phase 3, double-blind study of chemoradiotherapy with or without Pembrolizumab for the treatment of high-risk, locally advanced cervical cancer.

Uterus

Primary therapy

AGO-OP.6 (ECLAT)

Prof. Dr. med. Ingo Runnebaum
Beate Ludwig
 03641 - 9 329156

Jena Pelvic and Para-aortic Lymphadenectomy in Patients With Stage I or II Endometrial Cancer With High Risk of Recurrence

ENGOT-EN6 (RUBY)

Prof. Dr. med. Ingo Runnebaum
Beate Ludwig
 03641 - 9 329156

Jena Phase 3, Randomized, Double-blind, Multicenter Study of Dostarlimab (TSR-042) Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer (RUBY)

Neue Tumoroperation

Endometriumkarzinom
Prof. Dr. med. Bahriye Aktas
Iris Eberhardt
 0341 - 97 23937

Leipzig Neue Tumoroperation auf der Grundlage der ontogenetischen Anatomie zur Behandlung des frühen Endometriumkarzinoms: PMMR, TMMR+, tLNE

**1st line****DUO-E****Prof. Dr. med. Bahriye Aktas****Iris Eberhardt**

0341 - 97 23937

Leipzig A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination with Durvalumab, Followed by Maintenance Durvalumab with or without Olaparib in Patients with Newly Diagnosed Advanced or Recurrent Endometrial Cancer

PazoDoble II**Prof. Dr. med. Ingo Runnebaum****Beate Ludwig**

03641 - 9 329156

Jena Pazopanib versus Pazopanib plus Gemcitabine in patients with relapsed or metastatic uterine leiomyosarcomas or other uterine tumour: a multi-center, randomized phase-II clinical trial of the NOGGO and AGO

2nd line**DUO-E****Prof. Dr. med. Bahriye Aktas****Iris Eberhardt**

0341 - 97 23937

Leipzig A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination with Durvalumab, Followed by Maintenance Durvalumab with or without Olaparib in Patients with Newly Diagnosed Advanced or Recurrent Endometrial Cancer

Ovar**Primary therapy****DOSIS RCT****Dr. med. Franziska Nägler****Nadja Talhi**

0341 - 97 18541

Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

1st line**MAMOC****Prof. Dr. med. Ingo Runnebaum****Beate Ludwig**

03641 - 9 329156

Jena/Leipzig Rucaparib maintenance after Bevacizumab maintenance following Carboplatin based first line treatment chemotherapy in ovarian cancer patients

Prof. Dr. med. Bahriye Aktas**Iris Eberhardt**

0341 - 97 23937

2nd line**AGO-OVAR 2.29****Prof. Dr. med. Ingo Runnebaum****Beate Ludwig**

03641 - 9 329156

Jena Atezolizumab in Combination With Bevacizumab and Chemotherapy Versus Bevacizumab and Chemotherapy in Recurrent Ovarian Cancer - a Randomized Phase III Trial



MK-7902 PN 005-00	Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors
apl. Prof. Dr. med. Thomas Ernst Marina Liebing 03641 - 9 396675	

≥3rd line

AGO-OVAR 2.29	Jena Atezolizumab in Combination With Bevacizumab and Chemotherapy Versus Bevacizumab and Chemotherapy in Recurrent Ovarian Cancer - a Randomized Phase III Trial
Prof. Dr. med. Ingo Runnebaum Beate Ludwig 03641 - 9 329156	

MK-7902 PN 005-00	Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors
apl. Prof. Dr. med. Thomas Ernst Marina Liebing 03641 - 9 396675	

Prostata

Primary therapy

ADAM	Jena A Randomized, open-label, Phase 2 Study of Adjuvant Apalutamide or Standard of Care in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer After Radical Prostatectomy
Prof. Dr. med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970	

CRBP-TS-Studie	Leipzig Evaluation eines heimbasierten Trainings- und Versorgungsprogramms zur physischen und psychischen Stabilisierung bei kolorektal-, Brust- und Prostatakarzinom - Telemonitoring und Selfmanagement (CRB-TS)
Prof. Dr. med. Ines Gockel Nicole Kreuser 0341 - 97 12590	

DOSIS RCT	Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)
Dr. med. Franziska Näßler Nadja Talhi 0341 - 97 18541	

1st line

ADAM	Jena A Randomized, open-label, Phase 2 Study of Adjuvant Apalutamide or Standard of Care in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer After Radical Prostatectomy
Prof. Dr. med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970	

MK-3475-641	Jena Study of Pembrolizumab (MK-3475) Plus Enzalutamide Versus Placebo Plus Enzalutamide in Participants With Metastatic Castration-resistant Prostate Cancer
Prof. Dr.-med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970	



Hoden

Primary therapy

DOSIS RCT

Dr. med. Franziska Nägler
Nadja Talhi
 0341 - 97 18541

Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

Niere

Primary therapy

CA209-914

Prof. Dr.-med. Marc-Oliver Grimm
Dr. med. Susan Foller
Evelyn Meisel
 03641 - 9 329970

Jena A Study Comparing Nivolumab, Nivolumab in Combination With Ipilimumab and Placebo in Participants With Localized Kidney Cancer Who Underwent Surgery to Remove Part of a Kidney

DOSIS RCT

Dr. med. Franziska Nägler
Nadja Talhi
 0341 - 97 18541

Leipzig Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)

2nd line

Cabopoint
(F-FR-60000-023)

Prof. Dr.-med. Marc-Oliver Grimm
Dr. med. Susan Foller
Evelyn Meisel
 03641 - 9 329970

Jena A Phase II, Multicentre, Open-Label Study of Cabozantinib as 2nd Line Treatment in Subjects With Unresectable, Locally Advanced or Metastatic Renal Cell Carcinoma with Clear-Cell Component who Progressed after 1st Line Treatment with Checkpoint Inhibitors

Harnblase

Primary therapy

CA017-078

Prof. Dr. med. Marc-Oliver Grimm
Dr. med. Susan Foller
Evelyn Meisel
 03641 - 9 329970

Jena A Phase 3, Randomized, Study of Neoadjuvant Chemotherapy alone versus Neoadjuvant Chemotherapy plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab or Nivolumab and BMS-986205 in Participants with Muscle-Invasive Bladder Cancer

CA045-009

Prof. Dr. med. Marc-Oliver Grimm
Dr. med. Susan Foller
Evelyn Meisel
 03641 - 9 329970

Jena A Phase 3, Randomized, Study of Neoadjuvant and Adjuvant Nivolumab Plus Bempegaldesleukin (NKTR-214), Versus Nivolumab Alone Versus Standard of Care in Participants With Muscle-Invasive Bladder Cancer (MIBC) Who Are Cisplatin Ineligible



imVIGOR011	Jena	A Phase III, Double-Blind, Multicenter, Randomized Study of Atezolizumab (Anti-PDL1 Antibody) Versus Placebo as Adjuvant Therapy in Patients With High-Risk Muscle-Invasive Bladder Cancer Who Are ctDNA Positive Following Cystectomy
Prof. Dr. med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970		

MK-3475-676	Jena	A Phase 3, Randomized, Comparator-controlled Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Bacillus Calmette-Guerin (BCG) in Participants with High-risk Non-muscle Invasive Bladder Cancer (HR NMIBC) that is either Persistent or Recurrent Following BCG Induction or that is Naïve to BCG Treatment
Prof. Dr.-med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970		

1st line

CA209-901	Jena	A Phase 3, Open-label, Randomized Study of Nivolumab Combined With Ipilimumab, or With Standard of Care Chemotherapy, Versus Standard of Care Chemotherapy in Participants With Previously Untreated Unresectable or Metastatic Urothelial Cancer
Prof. Dr. med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970		

TIM	Jena	Instillation von Mistel-Extrakt vs. Mitomycin C bei Patienten mit oberflächlichem Blasenkarzinom
Prof. Dr. med. Marc-Oliver Grimm Dr. med. Susan Foller Evelyn Meisel 03641 - 9 329970		

Retinoblastom

Primary therapy

DOSIS RCT	Leipzig	Dose-intensified Image-guided Fractionated Stereotactic Body Radiation Therapy for Painful SpinalMetastases versus Conventional Radiation Therapy: a Randomised Controlled Trial (DOSIS RCT)
Dr. med. Franziska Nägler Nadja Talhi 0341 - 97 18541		

Zentrales Nervensystem

1st line

GLIOPT	Leipzig	Gliopatienten in der ambulanten Versorgung - Optimierung der psychosozialen Versorgung bei neuro-onkologischen Patienten / GLIOPT
Dr. med. Katja Jähne Bianka Schütze 0341 - 97 26173		

GLORIA	Leipzig	Single-arm, Dose-Escalation,Phase 1/2 Study of Olaptesed Pegol(NOX-A12 iin Combination with Irradiation in Inoperable or Partially Resected First-line Glioblastoma Patients with Unmethylated MGMT Promoter
Dr. med. Clemens Seidel Nadja Talhi 0341 - 97 18541		

**2nd line****GLIOPT**

Dr. med. Katja Jähne
Bianka Schütze
0341 - 97 26173

Leipzig Gliompatienten in der ambulanten Versorgung - Optimierung der psychosozialen Versorgung bei neuro-onkologischen Patienten / GLIOPT

MK-7902 PN 005-00

apl. Prof. Dr. med. Thomas Ernst
Marina Liebing
03641 - 9 396675

Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors

≥3rd line**MK-7902 PN 005-00**

apl. Prof. Dr. med. Thomas Ernst
Marina Liebing
03641 - 9 396675

Jena A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors

CUP**1st line****CUPISCO**
MX39795

apl. Prof. Dr. med. Thomas Ernst
Julia Locke
03641 - 9 396675

Jena A Phase II, Randomized, Active-Controlled, Multi-Center Study Comparing the Efficacy and Safety of Targeted Therapy or Cancer Immunotherapy Guided by Genomic Profiling Versus Platinum-Based Chemotherapy in Patients With Cancer of Unknown Primary Site Who Have Received Three Cycles of Platinum Doublet Chemotherapy



HÄMATOLOGISCHE NEOPLASIEN

Morbus Hodgkin

1st line

HD 21 **Jena/Leipzig** HD21 for Advanced Stages Treatment Optimization Trial in the First-line Treatment of Advanced Stage Hodgkin Lymphoma; Comparison of 6 Cycles of Escalated BEACOPP With 6 Cycles of BrECADD
apl. Prof. Dr. med. Sebastian Scholl
Sybille Münsterberg
03641 - 9 396684

Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

2nd line

MK4280-003 **Leipzig** A Phase 1/Phase 2 Clinical Study to Evaluate the Safety and Efficacy of a Combination of MK-4280 and Pembrolizumab (MK-3475) in Participants with Hematologic Malignancies
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

≥3rd line

CC-220 **Leipzig** A Phase 1, Multicenter, Open-label Study to Assess Safety, Pharmacokinetics, and Preliminary Efficacy of Iberdomide (CC-220), Alone and in Combination with anti-CD20 in Subjects with Relapsed or Refractory Lymphomas
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

MK4280-003 **Leipzig** A Phase 1/Phase 2 Clinical Study to Evaluate the Safety and Efficacy of a Combination of MK-4280 and Pembrolizumab (MK-3475) in Participants with Hematologic Malignancies
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

AGAVE-201 **Jena** AGAVE-201, A Phase 2, Open-label, Randomized, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Axatilimab at 3 Different Doses in Patients with Recurrent or Refractory Active Chronic Graft Versus Host Disease who have Received at least 2 Lines of Systemic Therapy
PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

Non-Hodgkin Lymphom

Primary therapy

ASTRAL II **Jena** A prospective Phase II clinical study to assess the efficacy and toxicity of high-dose chemotherapy followed by allogeneic stem cell transplantation as treatment of primary progressive and relapsed aggressive Non-Hodgkin Lymphoma
PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

**GRAPPA****PD Dr. med. Inken Hilgendorf****Daniela Hayde**

03641 - 9 396673

Jena Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG

1st line**Alternative-C****PD Dr. med. Ulf Schnetzke****Marina Liebing**

03641 - 9 396675

Jena A prospective multicenter Phase 2 Study of the Chemotherapy-free Combination of the intravenous Phosphatidylinositol-3-Kinase (PI3K) Inhibitor Copanlisib in Combination with Obinutuzumab in Patients with Previously Untreated Follicular Lymphoma (FL) and a High Tumor Burden

COPA-R-CHOP**Dr. med. Vladan Vucinic****Karolin Hubert**

0341 - 97 12634

Leipzig A prospective multicenter phase 2 study of copanlisib in combination with rituximab and CHOP chemotherapy (COPA-R-CHOP) in patients with previously untreated diffuse large B-cell lymphoma (DLBCL)

Morphosys FrontMIND**PD Dr. med. Ulf Schnetzke****Sybille Münsterberg**

03641 - 9 396684

Jena A Phase 3, multicenter, open-label, randomized trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP in highintermediate and high-risk patients with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

OptiIMATE**PD Dr. med. Ulf Schnetzke****Sybille Münsterberg**

03641 - 9 396684

Jena/Leipzig Optimizing MATrix as remission induction in PCNSL: De-escalated induction treatment in newly diagnosed primary CNS lymphoma – a randomized phase III trial

Dr. med Simone Heyn**Karolin Hubert**

0341 - 97 12634

2nd line**GOAL II****19-00153****PD Dr. med. Ulf Schnetzke****Sybille Münsterberg**

03641 - 9 396684

Jena A prospective, multicenter randomized phase II trial investigating Gemcitabine/Oxaliplatin/Rituximab with or without Tafasitamab (MOR208) for patients with relapsed/refractory Aggressive Lymphoma (GOAL II)

MOR208C204 - B-MIND**Dr. med. Vladan Vucinic****Karolin Hubert**

0341 - 97 12634

Leipzig A Phase 2/3 Randomized, Multicenter Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R-R-DLBCL) who are not eligible for High dose Chemotherapy (HDC) and Autologous Stem Cell Transplantation (ASCT) - B-MIND.

MK4280-003**Dr. med. Vladan Vucinic****Karolin Hubert**

0341 - 97 12634

Leipzig A Phase 1/Phase 2 Clinical Study to Evaluate the Safety and Efficacy of a Combination of MK-4280 and Pembrolizumab (MK-3475) in Participants with Hematologic Malignancies

**Pola-R-ICE**

PD Dr. med. Ulf Schnetzke
Sybille Münsterberg
 03641 - 9 396684

Jena An open-label, prospective Phase III clinical study to compare polatuzumab vedotin plus rituximab, ifosfamide, carboplatin and etoposide (Pola-R-ICE) with rituximab, ifosfamide, carboplatin and etoposide (R-ICE) alone as salvage therapy in patients with primary refractory or relapsed diffuse large B-cell lymphoma (DLBCL)

UniCAR02-T Studie

Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden

MOR208C204 - B-MIND

Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig A Phase 2/3 Randomized, Multicenter Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R-R-DLBCL) who are not eligible for High dose Chemotherapy (HDC) and Autologous Stem Cell Transplantation (ASCT) - B-MIND.

≥3rd line**CC-220**

Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig A Phase 1, Multicenter, Open-label Study to Assess Safety, Pharmacokinetics, and Preliminary Efficacy of Iberdomide (CC-220), Alone and in Combination with anti-CD20 in Subjects with Relapsed or Refractory Lymphomas

GOAL II**19-00153**

PD Dr. med. Ulf Schnetzke
Sybille Münsterberg
 03641 - 9 396684

Jena A prospective, multicenter randomized phase II trial investigating Gemcitabine/Oxaliplatin/Rituximab with or without Tafasitamab (MOR208) for patients with relapsed/refractory Aggressive Lymphoma (GOAL II)

MK4280-003

Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig A Phase 1/Phase 2 Clinical Study to Evaluate the Safety and Efficacy of a Combination of MK-4280 and Pembrolizumab (MK-3475) in Participants with Hematologic Malignancies

UniCAR02-T Studie

Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden

AGAVE-201

PD Dr. med. Inken Hilgendorf
Daniela Hayde
 03641 - 9 396673

Jena AGAVE-201, A Phase 2, Open-label, Randomized, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Axatilimab at 3 Different Doses in Patients with Recurrent or Refractory Active Chronic Graft Versus Host Disease who have Received at least 2 Lines of Systemic Therapy



Andere hämatologische Malignome

Primary therapy

GRAPPA Jena/Leipzig Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG
PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

1st line

GRAVITAS-309 Leipzig A Phase 2/3 Study of Itacitinib and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease
Dr. med. Georg-Nikolaus Franke
Karolin Hubert
0341 - 97 12634

2nd line

UniCAR02-T Studie Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

≥3rd line

UniCAR02-T Studie Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

AGAVE-201 Jena AGAVE-201, A Phase 2, Open-label, Randomized, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Axatilimab at 3 Different Doses in Patients with Recurrent or Refractory Active Chronic Graft Versus Host Disease who have Received at least 2 Lines of Systemic Therapy
PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673



Multiples Myelom

2nd line

DREAMM 8

Prof. Dr. med. Marie von Lilienfeld-Toal

Daniela Hayde

03641 - 9 396673

Jena A Phase III, Multicenter, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Belantamab Mafodotin in Combination with Pomalidomide and Dexamethasone (B-Pd) versus Pomalidomide plus Bortezomib and Dexamethasone (PVd) in Participants with Relapsed/Refractory Multiple Myeloma (DREAMM 8).

AlloRelapseMM

PD Dr. med. Inken Hilgendorf

Daniela Hayde

03641 - 9 396673

Jena Allogeneic stem cell transplantation vs. conventional therapy as salvage therapy for relapsed / progressive patients with multiple myeloma subsequent a first-line therapy

≥3rd line

CANOVA

Prof. Dr. med. Marie von Lilienfeld-Toal

Daniela Hayde

03641 - 9 396673

Jena A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

DREAMM 5

Song-Yau Wang

Karolin Hubert

0341 - 97 12634

Leipzig Platform Study of belantamab mafodotin (GSK2857916) as monotherapy and in combination with anti-cancer treatments in participants with RRMM

DREAMM 8

Prof. Dr. med. Marie von Lilienfeld-Toal

Daniela Hayde

03641 - 9 396673

Jena A Phase III, Multicenter, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Belantamab Mafodotin in Combination with Pomalidomide and Dexamethasone (B-Pd) versus Pomalidomide plus Bortezomib and Dexamethasone (PVd) in Participants with Relapsed/Refractory Multiple Myeloma (DREAMM 8).

Leukämien

Primary therapy

COMMANDS

Prof. Dr. med. Uwe Platzbecker

Karolin Hubert

0341 - 97 12634

Leipzig A phase 3, open-label, randomized study to compare the efficacy and safety of Luspatercept (ACE-536) versus Epoetin alfa for the treatment of anemia due to IPSS-R very low, low or intermediate risk myelodysplastic syndromes (MDS) in ESA naive subjects who require red blood cell transfusions

GRAPPA

PD Dr. med. Inken Hilgendorf

Daniela Hayde

03641 - 9 396673

Jena Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG

**1st line****AMG 103
20190360****apl. Prof. Dr. med. Sebastian Scholl
Gitta Bienert
03641 - 9 324216**

Jena A Randomized Study Comparing Blinatumomab Alternating With Low-intensity Chemotherapy Versus Standard of Care Chemotherapy for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia with Safety Run-in

Paloma**CPX351****PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673****Jena/Leipzig**

Primary compArison of Liposomal Anthracycline based treatment versus conventional care strategies before allogeneic stem cell transplantation in patients with higher risk MDS and oligoblastic AML – the PALOMA study

Prof. Dr. med. Uwe Platzbecker**Karolin Hubert
0341 - 97 12634****APOLLO****apl. Prof. Dr. med. Sebastian Scholl
Gitta Bienert
03641 - 9 324216****Jena/Leipzig**

A randomized Phase III study to compare arsenic trioxide ((ATO) combined to ATRA and idarubicin versus standard ATRA and anthracyclines-based chemotherapy (AIDA regimen) for patients with newly diagnosed, high-risk acute promyelocytic leukemia

Prof. Dr. med. Uwe Platzbecker**Karolin Hubert
0341 - 97 12634****ASC4First****Prof. Dr. med. Andreas Hochhaus
Dagmar Reuter
03641 - 9 396660****Jena**

A phase III, multi-center, open-label, randomized study of oral asciminib versus Investigator selected TKI in patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase

CLL 17**PD Dr. med. Ulf Schnetzke
Julia Locke
03641 - 9 396663****Jena/Leipzig**

A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib monotherapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia (CLL)

Dr. med Carmen Herling**Karolin Hubert
0341 - 97 12634****DAUNODouble****TUD-2DAUNO-058
apl. Prof. Dr. med. Sebastian Scholl
Julia Locke
03641 - 9 396663****Jena/Leipzig**

Randomized comparison between two dose levels of daunorubicin and between one versus two cycles of induction therapy for adult patients with acute myeloid leukemia ≤ 65 years

PD Dr. med. Sabine Kaiser**Karolin Hubert
03641 - 97 12634****EWALL-BOLD****apl. Prof. Dr. med. Sebastian Scholl
Gitta Bienert
03641 - 9 324216****Jena/Leipzig**

Phase II trial for the treatment of older patients with newly diagnosed CD19 positive, Ph/BCR-ABL negative B-precursor acute lymphoblastic leukemia with sequential dose reduced chemotherapy and Blinatumomab (EWALL-BOLD)

Dr. med. Vladan Vucinic**Karolin Hubert
0341 - 97 12634**



FGCL-4592-082	Leipzig	A Phase 3 Randomized Double-Blind Placebo-Controlled Study Investigating the Efficacy and Safety of Roxadustat (FG-4592) for Treatment of Anemia in Patients with Lower Risk Myelodysplastic Syndrome (MDS) with Low Red Blood Cell (RBC) Transfusion Burden (LTB)
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
GMALL 08/2013	Jena/Leipzig	Therapieoptimierung bei erwachsenen Patienten mit neu diagnostizierter akuter lymphatischer Leukämie (ALL) oder lymphoblastischem Lymphom (LBL) durch individualisierte, gezielte und intensivierte Therapie. Eine Phase IV-Studie mit einem phase III-Teil zur Evaluation der Sicherheit und Wirksamkeit von Nelarabin bei T-ALL
apl. Prof. Dr. med. Sebastian Scholl Gitta Bienert 03641 - 9 324216		
Dr. med. Vladan Vucinic Karolin Hubert 0341 - 97 12634		
GnG protocol	Leipzig	Randomized phase-III study to compare two schedules of gemtuzumab ozogamicin as adjunct to intensive induction therapy and to compare intensive postremission therapy double blinded with or without glasdegib in older patients with newly diagnosed AML
PD Dr. med. Sabine Kayser Karolin Hubert 0341 - 97 12634		
HeLeNe 18-03	Leipzig	Quizartinib and High-dose Ara-C plus Mitoxantrone in Relapsed/ Refractory AML with FLT3-ITD
PD Dr. med. Sabine Kayser Karolin Hubert 0341 - 97 12634		
IDEAL	Leipzig	A single-arm phase II multicenter study of IDH2 (AG 221) inhibitor in patients with IDH2 mutated myelodysplastic syndrome - IDEAL
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
LUCAS	Leipzig	A Phase II, Open-Label, Multicenter Study of Orally Administered CA-4948 for the Treatment of Anemia in Patients with Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS)
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
Mosaic	Leipzig	Midostaurin + Gemtuzumab Ozogamicin Combination in Firstline
TUD-MOSAIC-075	Jena	Standard Therapy for Acute Myeloid Leukemia
apl. Prof. Dr. med. Sebastian Scholl Marina Liebing 03641 - 9 396675		
PALOMA trial	Leipzig	Primary compArison of Liposomal Anthracycline based treatment versus conventional care strategies prior to allogeneic stem cell transplantation in patients with higher risk MDS or oligoblastic AML - the PALOMA study
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
SLN124-002	Leipzig	A randomised, single-blind, placebo-controlled, phase 1, single-ascending and multiple-dose study in adult subjects with alpha/beta-thalassaemia and very low- and low-risk myelodysplastic syndrome to investigate the safety, tolerability, pharmacokinetic, and pharmacodynamic response of SLN124
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
STIMULUS-AML1	Leipzig	A phase II multi-center, single arm study of MBG453 in combination with azacitidine and venetoclax for the treatment of Acute Myeloid Leukemia (AML) in adult patients unfit for chemotherapy
Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634		
VERONA	Leipzig	A Randomized, Double-Blind, Phase 3 Study Evaluating the Safety and Efficacy of Venetoclax in Combination with Azacitidine in Patients Newly Diagnosed with Higher-Risk Myelodysplastic Syndrome (Higher-Risk MDS)
PD Dr. med. Madlen Jentzsch Karolin Hubert 0341 - 97 12634		

**2nd line**

CA-4948-102 Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634	Leipzig A Phase 1, Open Label Dose Escalation Trial Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of Orally Administered CA-4948 in Patients with Acute Myelogenous Leukemia or Myelodysplastic Syndrome
DECIDER-2 apl. Prof. Dr. med. Sebastian Scholl Gitta Bienert 03641 - 9 324216	Jena Prospective randomized multicenter phase III trial of decitabine and Venetoclax administered in combination with all-trans retinoic acid or placebo in patients with acute myeloid leukemia who are ineligible for induction chemotherapy
ETAL3-ASAP Dr. med. Georg-Nikolaus Franke Karolin Hubert 0341 - 97 12634	Leipzig Evaluation of the impact of remission induction chemotherapy prior to allogeneic stem cell transplantation in relapsed and poor-response patients with AML (ETAL3-ASAP)
GMALL-MOLACT1-BLINA Dr. med. Vladan Vucinic Kitty Leuschel 0341 - 97 13133	Leipzig A multicenter, single-arm study to assess the efficacy, safety and tolerability of the BiTE (R) antibody blinatumomab in adult patients with minimal residual disease (MRD) of B-precursor acute lymphoblastic leukemia (Blast Successor Trial)
IDEAL Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634	Leipzig A single-arm phase II multicenter study of IDH2 (AG 221) inhibitor in patients with IDH2 mutated myelodysplastic syndrome - IDEAL
IDH2 Post Allo Dr. med. Georg-Nikolaus Franke Karolin Hubert 0341 - 97 12634	Leipzig Enasidenib as consolidation or salvage therapy for patients with IDH2 mutated AML or MDS following allogenic blood
LUCAS Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634	Leipzig A Phase II, Open-Label, Multicenter Study of Orally Administered CA-4948 for the Treatment of Anemia in Patients with Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS)
MANIFEST Prof. Dr. med. Uwe Platzbecker Karolin Hubert 0341 - 97 12634	Leipzig A Phase 1/2 Study of CPI-0610, a small Molecule of BET Proteins: Phase 1 (Dose Escalation of CPI-0610 in Patients with Hematological Malignancies) and Phase 2 (Dose Expansion of CPI-0610 with and without Ruxolitinib in Patients with Myelofibrosis)
PEMAZA TUD-PEMAZA-068 PD Dr. med. Ulf Schnetzke Gitta Bienert 03641 - 9 324216	Jena/Leipzig MRD-guided treatment with pembrolizumab and azacitidine in NPM1mut AML patients with an imminent hematological relapse
Prof. Dr. med. Uwe Platzbecker Nicole Thorn 0341 - 97 12658	



Q-Ham **Jena/Leipzig** Quizartinib and high-dose Ara-C plus Mixantrone in relapsed/
apl. Prof. Dr. med. Sebastian Scholl refractory AML with FLT3-ITD
Marina Liebing
 03641 - 9 396675

PD Dr. med. Sabine Kayser
Karolin Hubert
 0341 - 97 12634

TL-895-203 **Jena** An Open-Label, Multicenter, Phase 1b/2 Study of the Safety and
apl. Prof. Dr. med. Sebastian Scholl Efficacy of TL-895 Combined with KRT-232 in Subjects with Relap-
Julia Locke sed/Refractory (R/R) FLT3+ Acute Myeloid Leukemia (AML)
 03641 - 9 396663

UniCAR02-T Studie
Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für
 die Behandlung von Patienten mit CD123 positiven hämatolo-
 gischen und lymphatischen Malignomen mittels gentechnisch
 veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren
 (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit
 einem CD123-spezifischen Zielmodul (TM123) verabreicht werden

≥3rd line

CA-4948-102 **Leipzig** A Phase 1, Open Label Dose Escalation Trial Evaluating the Safety,
Prof. Dr. med. Uwe Platzbecker Pharmacokinetics, Pharmacodynamics, and Clinical Activity of
Karolin Hubert Orally Administered CA-4948 in Patients with Acute Myelogenous
 0341 - 97 12634 Leukemia or Myelodysplastic Syndrome

ASC4OPT
Prof. Dr. med. Andreas Hochhaus
Dagmar Reuter
 03641 - 9 396660

Jena A phase 3b, multi-center, open-label, treatment optimization
 study of oral asciminib in patients with Chronic Myelogenous
 Leukemia in chronic phase (CML-CP) previously treated with 2 or
 more tyrosine kinase inhibitors

TL-895-203 **Jena** An Open-Label, Multicenter, Phase 1b/2 Study of the Safety and
apl. Prof. Dr. med. Sebastian Scholl Efficacy of TL-895 Combined with KRT-232 in Subjects with Relap-
Julia Locke sed/Refractory (R/R) FLT3+ Acute Myeloid Leukemia (AML)
 03641 - 9 396663

UniCAR02-T Studie
Dr. med. Vladan Vucinic
Karolin Hubert
 0341 - 97 12634

Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für
 die Behandlung von Patienten mit CD123 positiven hämatolo-
 gischen und lymphatischen Malignomen mittels gentechnisch
 veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren
 (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit
 einem CD123-spezifischen Zielmodul (TM123) verabreicht werden



Andere bösartige Neoplasien des hämatopoetischen Systems

Primary therapy

ACE-536-MF-002

Independence Jena/Leipzig
Prof. Dr. med. Andreas Hochhaus
Maria Gerth
 03641 - 9 396671

A PHASE 3, DOUBLE-BLIND, RANDOMIZED STUDY TO COMPARE THE EFFICACY AND SAFETY OF LUSPATERCEPT (ACE-536) VERSUS PLACEBO IN SUBJECTS WITH MYELOPROLIFERATIVE NEOPLASM-ASSOCIATED MYELOFIBROSIS ON CONCOMITANT JAK2 INHIBITOR THERAPY AND WHO REQUIRE RED BLOOD CELL TRANSFUSIONS

Prof. Dr. med. Uwe Platzbecker

Karolin Hubert
 0341 - 9712634

Adore

Prof. Dr. med. Andreas Hochhaus
Maria Gerth
 03641 - 9 396671

Jena A randomized, open-label, phase I/II open platform study evaluating safety and efficacy of novel ruxolitinib combinations in myelofibrosis patients

KRT-232-109

Prof. Dr. med. Andreas Hochhaus
Gitta Bienert
 03641 - 9 324216

Jena An Open-Label, Multicenter, Phase 1b/2 Study of the Safety and Efficacy of KRT-232 Combined with Ruxolitinib in Patients with Primary Myelofibrosis (PMF), Post-Polyctyhemia Vera MF (Post-PV-MF), Or Post-Essential Thrombocythemia MF (Post-ET-MF) Who Have a Suboptimal Response to Ruxolitinib

GRAPPA

PD Dr. med. Inken Hilgendorf
Daniela Hayde
 03641 - 9 396673

Jena Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG

1st line

CETB115JDE01

ETB115 / Eltrombopag
XPAG-ITP
Dr. med. Thomas Stauch
Daniela Hayde
 03641 - 9 396673

Jena A Phase II, randomized (1:1) open label study to assess the efficacy and safety of eltrombopag in combination with dexamethasone compared to dexamethasone, as first-line treatment in adult patients with newly diagnosed immune thrombocytopenia (XPAG-ITP)

GRAVITAS-309

PD Dr. med. Inken Hilgendorf
Daniela Hayde
 03641 - 9 396673

Jena/Leipzig A Phase 2/3 Study of Itacitinib and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease

Dr. med. Georg-Nikolaus Franke

Karolin Hubert
 0341 - 97 12634

Incyte INCB 54828-203

Prof. Dr. med. Andreas Hochhaus
Marina Liebing
 03641 - 9 396675

Jena Incyte INCB 54828-203 A Phase 2, Open-Label, Monotherapy, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Myeloid/Lymphoid Neoplasms With FGFR1 Rearrangement



Manifest-2 A Phase 3, Randomized, Double-blind, Active-Control Study of
CPI 0610-04 Jena/Leipzig CPI-0610 and Ruxolitinib vs. Placebo and Ruxolitinib in JAK1 Treatment
Prof. Dr. med. Andreas Hochhaus Naive MF Patients
Gitta Bienert
03641 - 9 324216

Prof. Dr. med. Uwe Platzbecker
Karolin Hubert
0341 - 97 12634

SLN124-002 Leipzig A randomised, single-blind, placebo-controlled, phase 1, single-ascending and multiple-dose study in adult subjects with alpha/beta-thalassæmia and very low- and low-risk myelodysplastic syndrome to investigate the safety, tolerability, pharmacokinetic, and pharmacodynamic response of SLN124
Prof. Dr. med. Uwe Platzbecker
Karolin Hubert
0341 - 97 12634

2nd line

IMG-7289-CTP-201 Jena A Phase 2 Multi-Center, Open Label Study to Assess the Safety, Efficacy and Pharmacodynamics of IMG-7289 in Patients with
Imago
Prof. Dr. med. Andreas Hochhaus
Maria Gerth
03641 - 9 396671

TL-895-201 Jena A Phase 2, Open-label, Multicenter Study of TL-895 in Subjects with Relapsed/Refractory Myelofibrosis, Janus Kinase Inhibitor Intolerant Myelofibrosis and Janus Kinase Inhibitor Treatment Ineligible Myelofibrosis
Prof. Dr. med. Andreas Hochhaus
Gitta Bienert
03641 - 9 324216

UniCAR02-T Studie Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

≥3rd line

IMG-7289-CTP-201 Jena A Phase 2 Multi-Center, Open Label Study to Assess the Safety, Efficacy and Pharmacodynamics of IMG-7289 in Patients with Essential Thrombocythemia
Imago
Prof. Dr. med. Andreas Hochhaus
Maria Gerth
03641 - 9 396671

MANIFEST Leipzig A Phase 1/2 Study of CPI-0610, a small Molecule of BET Proteins: Phase 1 (Dose Escalation of CPI-0610 in Patients with Hematological Malignancies) and Phase 2 (Dose Expansion of CPI-0610 with and without Ruxolitinib in Patients with Myelofibrosis)
Prof. Dr. med. Uwe Platzbecker
Karolin Hubert
0341 - 97 12634

UniCAR02-T Studie Leipzig Multizentrische, offene Phase I Studie mit Dosissteigerungen für die Behandlung von Patienten mit CD123 positiven hämatologischen und lymphatischen Malignomen mittels gentechnisch veränderten T-Zellen, die universelle chimäre Antigen-Rezeptoren (UniCAR02-T) auf der Oberfläche tragen, und in Kombination mit einem CD123-spezifischen Zielmodul (TM123) verabreicht werden
Dr. med. Vladan Vucinic
Karolin Hubert
0341 - 97 12634

**AGAVE-201**

PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

Jena AGAVE-201, A Phase 2, Open-label, Randomized, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Axatilimab at 3 Different Doses in Patients with Recurrent or Refractory Active Chronic Graft Versus Host Disease who have Received at least 2 Lines of Systemic Therapy

Stammzelltransplantation

Primary therapy

GRAPPA

PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

Jena Graft vs Host Disease Prophylaxis in unrelated donor transplantation: a randomized clinical trial comparing PTCY vs ATG

1st line

GRAVITAS-309

PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

Jena/Leipzig A Phase 2/3 Study of Itacitinib and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease

Dr. med. Georg-Nikolaus Franke

Karolin Hubert
0341 - 97 12634

IDUNN

PD Dr. med. Inken Hilgendorf
Gitta Bienert
03641 - 9 324216

Jena/Leipzig A Randomised, Open-label, Multicentre, Phase 3 Trial of First-line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid-refractory Acute Graft-versus-host Disease After Allogeneic Haematopoietic Stem Cell Transplantation / IDUNN

Dr. med. Georg-Nikolaus Franke

Karolin Hubert
0341 - 97 12634

2nd line

IDUNN

PD Dr. med. Inken Hilgendorf
Gitta Bienert
03641 - 9 324216

Jena/Leipzig A Randomised, Open label, Multicentre, Phase 3 Trial of First line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid refractory Acute Graft versus host Disease After Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial)

Dr. med. Georg-Nikolaus Franke

Karolin Hubert
0341 - 97 12634

≥3rd line

AGAVE-201

PD Dr. med. Inken Hilgendorf
Daniela Hayde
03641 - 9 396673

Jena AGAVE-201, A Phase 2, Open-label, Randomized, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Axatilimab at 3 Different Doses in Patients with Recurrent or Refractory Active Chronic Graft Versus Host Disease who have Received at least 2 Lines of Systemic Therapy



PSYCHOONKOLOGISCHE STUDIEN

LUPE Prof. Dr. phil. Anja Mehnert-Theuerkauf Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Längsschnittanalyse des psycho-onkologischen Unterstützungsbedarfs bei Patienten und deren Angehörigen stratifiziert nach biopsychosozialen Einflussfaktoren (LUPE)
OptiScreen Prof. Dr. phil. Anja Mehnert-Theuerkauf Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Optimierte psychoonkologische Versorgung durch einen interdisziplinären Versorgungsalgorhythmus - vom Screening zur Intervention (OptiScreen)
Palli-Studie Prof. Dr. Andreas Hinz Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Gesundheitsbezogene Lebensqualität in der Onkologie und Palliativmedizin: Die Beziehung zwischen Wichtigkeits- und Zufriedenheitsurteilen
WAG-ES! Dr. rer. med. Antje Lehmann-Laue 0341 - 97 15415	Leipzig Wege ebnen für Männer - Geschlechtsspezifische Zuweisung und Konzepte für die ambulante Krebsberatung
Onko-STEP Dr. rer. med. Kristina Geue 0341 - 97 15438	Leipzig Wirksamkeit der kognitiv-behavioralen Online-Schreibtherapie Onko-STEP für Krebspatienten im jungen Erwachsenenalter - eine randomisierte kontrollierte Studie
REDUCT Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Web-based Mindfulness and Skills-Based Distress REDUCTION for cancer patients: A multi-center, randomized, controlled intervention study
Peer2me Dr. rer. nat. Diana Richter Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Pilotierung eines Peer-Mentorings für Krebspatienten im jungen Erwachsenenalter - erste Erprobung der Machbarkeit und Akzeptanz
Fatigue Prof. Dr. phil. Anja Mehnert-Theuerkauf Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Pilot study on a cognitive behavioural therapy (CBT) web based intervention on fatigue in survivors of Hodgkin lymphoma
SALUT Dr. rer. nat. Peter Esser Dr. med. Jochen Ernst 0341 - 97 15415	Leipzig Trauma- und belastungsbezogene Störungen bei hämatologischen Krebspatienten nach Stammzelltransplantation: eine Interview-basierte Studie anhand aktualisierter diagnostischer Kriterien



PÄDIATRISCHE STUDIEN

Kopf und Hals

Primary therapy

NPC-2016

Leipzig A multicenter registry for nasopharyngeal cancer in children,

Prof. Dr. med. Holger Christiansen

adolescents and young adults

Kerstin Faulhaber

0341 - 97 26173

STEP Register

Leipzig Seltene Tumorerkrankungen in der Pädiatrie (STEP) Register zur

Prof. Dr. med. Holger Christiansen

Erfassung von seltenen Tumoren bei Kindern und Jugendlichen

Kerstin Faulhaber

0341 - 97 26173

Darm

Primary therapy

GPOH-MET-Register

Jena/Leipzig

GPOH-MET-Register Register zur Erfassung maligner endokriner

apl. Prof. Dr. med. Bernd Gruhn

Tumoren im Kindes- und Jugendalter

Berit Zellner

03641 - 9 329515

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

Leber / Gallenblase

Primary therapy

LTR

Jena/Leipzig

Register für Lebertumoren bei Kindern und Jugendlichen

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

1st line

PHITT

Leipzig Paediatric Hepatic International Tumour Trial

Dr. med. Lars Fischer

Kerstin Faulhaber

0341 - 97 26173



Knochen, Gelenkknorpel, Binde- und Weichteilgewebe

iEER Leipzig Internationales Euro Ewing Register

Dr. med. Hagen Graf Einsiedel

Kerstin Faulhaber

0341 - 97 26173

Primary therapy

ch14.18 - Haplo Registry Jena Registry of the therapeutic impact of Dinutuximab beta after apl. Prof. Dr. med. Bernd Gruhn Haploididentical stem cell transplantation in children with relapsed or refractory neuroblastoma
Berit Zellner
03641 - 9 329515

NB Registry 2016 Jena/Leipzig Registry for neonates, infants, children, adolescents, and adults apl. Prof. Dr. med. Bernd Gruhn with newly diagnosed and/or relapsed neuroblastic tumors
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

1st line

CWS-2007-HR Leipzig A randomised phase-III trial of the Cooperative Weichteilsarkom Prof. Dr. med. Holger Christiansen Studiengruppe for localised high-risk Rhabdomyosarcoma and Kerstin Faulhaber localised Rhabdomyosarcoma-like Soft Tissue Sarcoma in children, adolescents, and young adults
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SoTiSaR Jena/Leipzig CWS-Register SoTiSaR A Registry for soft tissue sarcoma and other apl. Prof. Dr. med. Bernd Gruhn soft tissue tumours in children, adolescents, and young adults
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

COSS-Register Jena/Leipzig COSS-Registry: Clinical Registry for children, adolescents and apl. Prof. Dr. med. Bernd Gruhn adults with Osteosarcoma and Bone Tumors
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

2nd line

METRO-NB 2012 Leipzig Phase II Trial of Metronomic treatment in children and adolescents Prof. Dr. med. Holger Christiansen with recurrent or progressive neuroblastoma
Kerstin Faulhaber
0341 - 97 26173



Andere bösartige Neoplasien der Haut

Primary therapy

STEP Register Jena/Leipzig Seltene Tumorerkrankungen in der Pädiatrie (STEP) Register zur Erfassung von seltenen Tumoren bei Kindern und Jugendlichen
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

Solide Tumoren

Sarkome

Primary therapy

EWING 2008 Jena International Euro Ewing - Registry
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Hämatologische Neoplasien

2nd line

rEECur Jena/Leipzig International Randomised Controlled Trial of Chemotherapy for the Treatment of Recurrent and Primary Refractory Ewing Sarcoma
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

Psychoonkologische Studien

Ovar

1st line

MAKEI V Leipzig Multicentre prospective trial for extracranial malignant germ cell tumours including a randomized comparison of Carboplatin and Cisplatin
Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

Pädiatrische Studien

Niere

Primary therapy

**HLH Registry**

Leipzig A registry for hemophagocytic lymphohistiocytosis (HLH)

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

Randomet 2017

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Jena

Randomisierte, multizentrische, offene Phase III, Äquivalenzstudie für Patienten mit Nierentumor des Kindesalters im Stadium IV zum Vergleich der präoperativen Chemotherapie bestehend aus Vincristin, Actinomycin - D und Doxorubicin mit der primären Chemotherapie bestehend aus Vincristin, Carboplatin und Etoposid

1st line**SIOP 2001 / GPOH**

Jena/Leipzig

THERAPIEOPTIMIERUNGSSUDIE ZUR BEHANDLUNG VON KIN-
DERN UND JUGENDLICHEN MIT EINEM NEPHROBLASTOM

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

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SIOP-RTSG 2016

Dr. med. Lars Fischer

Kerstin Faulhaber

0341 - 97 26173

Leipzig Treatment for Pediatric Patients With Renal Tumours According to the International SIOP Renal Tumour Study Group (RTSG) 2016 UMBRELLA

Retinoblastom**Primary therapy****RB-Registry**

Leipzig RB-registry: a clinical registry for data on epidemiology and clinical course of retinoblastoma and pediatric eye tumors

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

Zentrales Nervensystem**MNP Int-R**

Leipzig Molecular Data Generation and Clinical Follow-up within the

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

International Molecular Neuropathology Registry



Primary therapy

I - HIT - MED apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena International HIT - MED - Registry for children, adolescents and young adults with medulloblastoma, ependymal and pineal tumors
LOGGIC Core Prof. Dr. med. Holger Christiansen Kerstin Faulhaber 0341 - 97 26173	Leipzig LOGGIC Core BioClinical Data Bank LOGGIC: Low Grade Glioma In Children
PNET 5 MB apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena An international prospective trial on medulloblastoma in children older than 3 to 5 years with wnt biological profile, average - risk biological profile, or tp53 mutation, and registry for mb occurring in the context of genetic predisposition
PTT2.0 Prof. Dr. med. Holger Christiansen Kerstin Faulhaber 0341 - 97 26173	Leipzig Pediatric Targeted Therapy 2.0 - refining diagnosis and analyzing targets in progressive and relapsed pediatric malignancies - brain tumors, sarcoma and peripheral tumors of the nervous system

1st line

CPT-SIOP-2009 apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena/Leipzig Intercontinental Multidisciplinary Registry and Treatment Optimization Study for Patients with Choroid Plexus Tumors
Prof. Dr. med. Holger Christiansen Kerstin Faulhaber 0341 - 97 26173	
EU-RHAB apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena/Leipzig multinational registry for rhabdoid tumors of any anatomical site
Prof. Dr. med. Holger Christiansen Kerstin Faulhaber 0341 - 97 26173	
HIT HGG 2013 apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena Intercontinental Multidisciplinary Registry and Treatment Optimization Study for Patients with Choroid Plexus Tumors
HIT-HGG-2013 Prof. Dr. med. Holger Christiansen Kerstin Faulhaber 0341 - 97 26173	Leipzig International cooperative Phase III trial of the HIT-HGG study group for the treatment of high grade glioma, diffuse intrinsic pontine glioma, and gliomatosis cerebri in children and adolescents < 18 years



HIT-LOGGIC Register Jena/Leipzig Prospektives multizentrisches Register für Kinder und Jugendliche mit einem niedrig-gradigen Gliom
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

KRANIOPHARYNGEOM Registry 2019 Jena/Leipzig Multicenter registry for patients with childhood-onset craniopharyngioma, xanthogranuloma, cysts of Rathke's pouch,meningioma, pituitary adenoma, arachnoid cysts
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

SIOP Ependymoma II Jena/Leipzig An international Clinical Program for the diagnosis and treatment of children, adolescents and young adults with ependymoma
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

SIOP PNET 5 Medulloblastoma
Leipzig
Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

AN INTERNATIONAL PROSPECTIVE TRIAL ON MEDULLOBLASTOMA (MB) IN CHILDREN OLDER THAN 3 TO 5 YEARS WITH WNT BIOLOGICAL PROFILE (PNET 5 MB - LR and PNET 5 MB - WNT-HR), AVERAGE-RISK BIOLOGICAL PROFILE (PNET 5 MB -SR), OR TP53 MUTATION, AND REGISTRY FOR MB OCCURRING IN THE CONTEXT OF GENETIC PREDISPOSITION

2nd line

HIT-REZ-REGISTER Jena/Leipzig Multinationales multizentrisches Register für Kinder, Jugendliche und junge Erwachsene mit therapierefraktären, progredienten oder rezidivierten Medulloblastomen, Pineoblastomen, primitiv neuroektodermalen Tumoren des ZNS (ZNS-PNETs) und Ependymomen
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Cornelia Krumbholz
0341 - 97 26173

Schilddrüse

Primary therapy

GPOH-MET-Register Leipzig GPOH-MET-Register Register zur Erfassung maligner endokriner Tumoren im Kindes- und Jugendalter
Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173



Non-Hodgkin Lymphoma

Primary therapy

Durvalumab / Tremelimumab **Jena** Phase I/II, Open - Label, Multicentre Study to evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

INFORM **Jena/Leipzig** INFORM - INDividualized Therapy FO r Relapsed Malignancies in Childhood
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

NHL-BFM Registry 2012 **Jena/Leipzig** Registry of the NHL-BFM study group for all subtypes of Non-Hodgkin lymphoma diagnosed in children and adolescents
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

1st line

B - NHL 2013 **Jena/Leipzig** Treatment protocol of the NHL-BFM and the NOPHO study groups for mature aggressive B-cell lymphoma and leukemia in children and adolescents
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

LBL 2018 **Jena/Leipzig** International cooperative treatment protocol for children and adolescents with lymphoblastic lymphoma
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

MAKEI V **Jena** Multicentre prospective trial for extracranial malignant germ cell tumours including a randomized comparison of Carboplatin and Cisplatin
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

IDUNN **Jena** A Randomised, Open - label, Multicentre, Phase III Trial of First - line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid - refractory Acute Graft - versus - host Disease after Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial)
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515



Andere hämatologische Neoplasien

Primary therapy

Durvalumab / Tremelimumab **Jena** Phase I/II, Open - Label, Multicentre Study to evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

INFORM **Leipzig** INFORM - INdividualized Therapy FOr Relapsed Malignancies in Childhood
Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

PRST **Leipzig** PRST Pädiatrisches Register für Stammzelltransplantation
Dr. med. Jörn-Sven Kühl
Kerstin Faulhaber
0341 - 97 26173

EuroNet-PHL-C2 **Jena** Second international trial for classical Hodgkin's lymphoma in children and adolescents (registry)
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

1st line

MAKEI V **Jena** Multicentre prospective trial for extracranial malignant germ cell tumours including a randomized comparison of Carboplatin and Cisplatin
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

IDUNN **Jena** A Randomised, Open - label, Multicentre, Phase III Trial of First - line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid - refractory Acute Graft - versus - host Disease after Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial)
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Leukämien

Primary therapy

ALL-REZ BFM **Jena/Leipzig** Observational study and biobank for relapsed ALL in children and adolescents
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173



AML SCT BFM Jena **Multicenter therapy concept for allogeneic SCT in children, adolescents and young adults with relapsed or refractory AML (registry)**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

CML-pead II Register Jena/Leipzig **Protocol for standardized diagnostic procedures, registration, and treatment recommendations in children and adolescents with Philadelphia chromosome-positive chronic myeloid leukemia (CML)**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Hagen Graf Einsiedel
Kerstin Faulhaber
0341 - 97 26173

Durvalumab / Tremelimumab Jena **Phase I/II, Open - Label, Multicentre Study to evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

INFORM Leipzig **INFORM - INdividualized Therapy FOr Relapsed Malignancies in Childhood**
Prof. Dr. med. Holger Christiansen
Kerstin Faulhaber
0341 - 97 26173

Interfant 06 Jena **International Cooperative Treatment Protocol for Infants in the First Year of Life with Acute Lymphoblastic or Biphenotypic Leukemia (Registry)**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

MLDS 2018 Jena **Phase III Clinical Trial for CPX - 351 in Myeloid Leukemia in Children with Down Syndrome 2018**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Register AML-BFM 2017 Jena/Leipzig **Register for the registration of acute myelogenous leukaemia in children and adolescents**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173

1st line

AIEOP BFM ALL 2017 Jena/Leipzig **International collaborative treatment protocol for children and adolescents with acute lymphoblastic leukemia**
apl. Prof. Dr. med. Bernd Gruhn
Berit Zellner
03641 - 9 329515

Dr. med. Lars Fischer
Kerstin Faulhaber
0341 - 97 26173



EsPhALL 2017 apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena International phase 3 trial in Philadelphia chromosome - positive acute lymphoblastic leukemia testing imatinib in combination with two different cytotoxic chemotherapy backbones
EsPHALL2017/COGALL1631 Leipzig Dr. med. Hagen Graf Einsiedel Kerstin Faulhaber 0341 - 97 26173	International phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (PH+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones
EWOG-MDS 2006 Dr. med. Jörn-Sven Kühl Kerstin Faulhaber 0341 - 97 26173	Leipzig Prospective non-randomized multi-center study for epidemiology and characterization of Myelodysplastic Syndromes (MDS) and Juvenile Myelomonocytic Leukemia (JMML) in childhood
MAKEI V apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena Multicentre prospective trial for extracranial malignant germ cell tumours including a randomized comparison of Carboplatin and Cisplatin
IDUNN apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena A Randomised, Open - label, Multicentre, Phase III Trial of First - line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid - refractory Acute Graft - versus - host Disease after Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial)

2nd line

ALL SCTped 2012 FORUM apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena/Leipzig Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia
Dr. med. Jörn-Sven Kühl Kerstin Faulhaber 0341 - 97 26173	
IntRe-ALL-HR 2010 apl. Prof. Dr. med. Bernd Gruhn Berit Zellner 03641 - 9 329515	Jena/Leipzig International Study for Treatment of High Risk Childhood Relapsed ALL 2010

Dr. med. Lars Fischer
Kerstin Faulhaber
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Andere bösartige Neoplasien des hämatopoetischen Systems

Sichelzellregister Jena/Leipzig Register Sichelzellerkrankheit

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

Primary therapy

Durvalumab / Tremelimumab Jena Phase I/II, Open - Label, Multicentre Study to evaluate the Safety,

apl. Prof. Dr. med. Bernd Gruhn Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy

Berit Zellner or Durvalumab in Combination with Tremelimumab in Pediatric

Patients with Advanced Solid Tumors and Hematological Malignancies

03641 - 9 329515

1st line

EWOG-MDS 2006

Dr. med. Jörn-Sven Kühl

Kerstin Faulhaber

0341 - 97 26173

Leipzig Prospective non-randomized multi-center study for epidemiology and characterization of Myelodysplastic Syndromes (MDS) and Juvenile Myelomonocytic Leukemia (JMML) in childhood

MAKEI V

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Jena Multicentre prospective trial for extracranial malignant germ cell tumours including a randomized comparison of Carboplatin and Cisplatin

IDUNN

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Jena A Randomised, Open - label, Multicentre, Phase III Trial of First - line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid - refractory Acute Graft - versus - host Disease after Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial)



Andere Neoplasien

Primary therapy

Fanconi Anemia

Registry 01

Jena/Leipzig

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Fanconi Anemia Registry 01 Natural History Study to describe the clinical course of FA and to define genetic and environmental modifiers. Fanconi anemia (FA) is a rare inherited BMFS characterized by congenital and endocrine anomalies, impaired hematopoiesis, and cancer predisposition.

Dr. med. Lars Fischer

Kerstin Faulhaber

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Kraniopharyngeom 2007

Leipzig

Kraniopharyngeom 2007: Multicenter prospective study of children and adolescents with Craniopharyngeoma

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

EWOG-SAA 2010

Leipzig

Genetic and Immunological Characterization of Acquired Severe

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

Aplastic Anemia (SAA) in Children and Adolescents

HLH Registry

Jena/Leipzig

A registry for hemophagocytic lymphohistiocytosis (HLH)

apl. Prof. Dr. med. Bernd Gruhn

Berit Zellner

03641 - 9 329515

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

1st line

LCH-REG-DE 2013

Leipzig

Deutsches Register für Langerhanszell Histiozytosen im Kindes-

Prof. Dr. med. Holger Christiansen

Kerstin Faulhaber

0341 - 97 26173

und Jugendalter











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