EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA), Scientific Committee members and experts

Public declaration of interests

I, **Florian Lasch**

Organisation/Company: Hannover Medical School

Country: Germany

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No Interest Declared

2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

Clinics at Hannover Medical School may participate in industry sponsored trials. I am not involved in these trials and do have no further knowledge about these. The following is the list of investigator initiated drug trials in which the institute of biostatistics is involved regarding planning, conduct, or analysis, or in function as members of a DSMB:

2008-000706-36: Optimization of treatment for patients with chronic hepatitis C infected with HCV-genotype 2 or 3: 12 vs. 24 weeks of Treatment EXtension for patients without rapid virological response (OPTEX 2/3) (Prüfplancode: P05498)

2009-012436-32: IA multicentre, randomized, open-labelled study to steer immunosuppressive and antiviral therapy by measurement of virus-(CMV, ADH; HSV) specific T cells in addition to determination of trough levels of immunosuppressants in pediatric kidney allograft recipients. An explorative study. (Prüfplancode: IVIST01)

2008-005433-30: 1st-Line Docetaxel-Platin Chemotherapie alleine oder in Kombination mit Enoxaparin bei Patienten mit lokal fortgeschrittenem oder metastasiertem nicht-kleinzelligem Bronchial-Karzinom. Eine Phase III Studie (Prüfplan-Code: ENOXANSCLC)

2008-005560-13: A multicenter randomized study comparing the efficacy of pegylated interferon-alfa-2a plus placebo vs. pgylated interferon-alfa-2a plus tenofovir for the treatment of chronic delta hepatitis (Prüfplancode: Hep-Net-HIDIT-2)

2009-014396-43: A Single arm, open-label multicenter phase II trial of temsirolimus in patients with relapsed/recurrent squamous cell cancer of the Head and Neck (HNSCC) (Prüfplan-Code: HN001 TEMHEAD)

2007-005503-17: Randomisierte, multizentrische Doppelblindstudie der Phase III bei Patienten nach Nierentransplantation mit einer akuten zellulären Rejektion im Nierentransplantat nach Banff-Kriterien (mindestens Grad IA) oder Banff Borderline Rejektion mit simultanem Kreatininanstieg (> 20% über baseline Kreatinin) und histologischem Nachweis eines nodulären Infiltrates mit CD20-positiven Lymphozyten zum Nachweis der Überlegenheit einer Therapie mit Steroidboli plus Rituximab/MabThera® im Vergleich zu einer alleinigen Therapie mit Steroidboli bezüglich der Nierenfunktion nach einem Jahr (Prüfplancode: 200710602)

2008-005862-30: Pre-emptive therapy of acute graft versus host disease according to specific proteomic patterns after allogeneic hematopoietic stem cell transplantation. (Prüfplancode: MHH-Pre-GvHD-001)

2009-017052-27: old title: A randomized, controlled, observer-blind, phase II study to evaluate the immunogenicity, safety and tolerability of two doses of two candidate H1N1 influenza vaccines in immunocompromised adults who have undergone solid organ transplantation or bone marrow transplantation and healthy adults (Prüfplancode: 200910H1N1MHH) /new title since 1/10: A Phase II Study to evaluate the immunogenicity, safety and tolerability of a H1N1 Influenze vaccine in immunocompromised adults who have undergone solid organ transplantation or bone marrow transplantation and in age-matched health volunteers (Focetria TX) (Ende 5/11)

2009-014383-18: A single arm, open-label multicenter phase II trial of everolimus in patients with relapsed/refractory germ cell caner (RADIT) (Prüfplancode: CRAD001CDE21T)

2010-022871-78: A Phase II Study to evaluate the immunogenicity, safety and tolerability of a seasonal influenza vaccine including H1N1 in immunocompromised adults who have undergone solid organ transplantation of bone marrow transplantation and in age-matched healthy volunteers (Prüfplan-Code: 201009H1N1MHH)

2010-021944-17: Randomized, multi-centre, Phase II trial to compare the event-free survival of Clofarabine/ARA-C (ClAraC) or of FLAMSA treatment in patients with high risk AML or advanced MDS scheduled for allogeneic stem cell transplantation (Prüfplancode: ClAraC-SCT-01)

2010-019884-12: Induction of Fibrosis Regression regarding Chronic Hepatitis B Infection (Prüfplancode: INFIRE-001)

2011-004168-30: A randomized phase II trial comparing pazopanib with doxorubicin as first line treatment in elderly patients with metastatic or advanced soft tissue sarcoma (Prüfplancode: STS001)

2011-003238-15: Quality of analgesia and side effect incidence and severity during postoperative pain management with Palexia® compared to Targin® (Prüfplancode: Schaefers0711)

2012-001352-19: BE-RELACS-trial: Biomarkers Explaining Induction of Alloimmunity and RELevance of Acute Rejections. A randomized, open label, single centre, biomarker trial (Prüfplancode: 20120309-01)

2012-003234-16: Randomized Double Blind Placebo-controlled Study to Demonstrate That Antibiotics Are Not Needed in Moderate Acute Exacerbations of COPD - The ABACOPD Study (Prüfplancode: 002/2012)

2012-005002-22: Prospective double-blind placebo-controlled randomized clinical trial for demonstration of efficacy of ACEMg to protect residual hearing (FP7-2012)

2013-005326-38: DIGIT-HF: Prospektive randomisierte Studie zum Vergleich einer Digitoxin basierten Behandlung bei Patienten mit KHK und chronischer Herzinsuffizienz im Stadium NYHA II/IV oder Vorhofflimmern zum Nachweis der Verbesserung der Endothelfunktion und der Inflammation.

2013-001081-42: Interferon-free Treatment of Acute Genotype 1 Hepatitis C Virus Infection with Ledipasvir/Sofosbuvir Fixed-Dose Combination - The HepNet Acute HCV IV Study (Prüfplancode: HepNet-aHCV-IV)

2013-002825-52: Monozentrische, offene, einarmige Studie der Phase IIa bei Patienten nach Nierentransplantation mit einer akuten T-Zellvermittelten Rejektion im Nierentransplantat nach Banff-Kriterien (Grad IA und IB) ohne (Stufe I) oder mit (Stufe II) Verschlechterung der Transplantatfunktion zum Nachweis der Wirksamkeit einer Therapie mit Canakinumab bezüglich der Rückbildung der Infiltrate in der Transplantatbiopsie.

2014-003313-28: SGLT2 inhibition with empagliflozin in patients with type 2 diabetes mellitus: Influences on left ventricular mass, function, and cardiac lipid content (EMPATROPHY)

2016-000564-42: Treatment of Tourette syndrome with the cannabis extract nabiximols ? a randomized, placebo-controlled, double-blind, multicenter trial (Canna-Tics)

2016-000825-38:): SGLT2-inhibition with Empagliflozin reduces progression of diabetic retinopathy in patients with high risk of diabetic macular edema ? a randomized, active-controlled, doubleblind, monocenter parallel-group trial (SUPER)

2017-000394-36: : Influences of angiotensin-neprilysin inhibition with LCZ696 (Valsartan/Sacubitril) on centrally generated sympathetic activity in heart failure patients ? a single-centre, active-controlled (Valsartan), double-blind crossover study in randomized sequence of treatment (Arni-Sy)

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.
- Not to disclose (or authorise any other person to disclose) in any way to any third party any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	Florian Lasch
Date:	2020-02-19

For Definitions of activities etc, refer to Policy on Handling of Conflicts of Interest / Electronic DOI template