CURRICULUM VITAE

Name: Katherine Hester, MD, PhD, dipl. Health Economist, RAC - aka Ruster

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Summary of Experience:

Katherine Hester, MD, **PhD** has over 12 years of post-doctoral academic, pharmaceutical R & D experience in the therapeutic areas of internal medicine, anti-inflammatory, and transplantation, as well as a PhD in special immunology (Flavivirus).
She also has clinical patient experience in internal medicine, and intensive care/end of life issues.
Dr. Hester's clinical research experience ranges from an early phase start-up biotech company as the only medical resource for clinical development and safety, strategic planning, as well as an MD at the top five global pharmaceutical companies.
Dr. Hester is an expert in medical writing. She is an expert at planning and providing constructive comments and finding missing information. During her work at Y's, she developed clinical development plans, among them one for renal transplantation. She collaborated closely with one of her references, Dr. Beth Squiers, a transplant surgeon, and the CEO (Tim Schroeder) of a CRO well known in the transplantation arena: CTI, Ohio. She also presented to the chief of the transplantation department at Tampa General Hospital. During her work at Aventis (now Sanofi), her direct supervisor was a Prof. of nephrology and she published Paar WD, Hester Katherine, Schinzel H, **"**Pharmacokinetics of LMW heparin in renal insufficiency**"** J Kardiol 2004 (Dr. Hester wrote the whole article). During her work at Merck and Y's, she updated Investigator Brochures and was part of an IND submission.
In devices, she was the clinical responsible for an IDE stage product with many preclinical issues providing medical expertise.

Summary of her development experience:

Product	**Function**	**Status**
Cancer antibody	*advisor and wrote protocol*	*IND*
Cyclosporine	Ph II trial principal investigator initiated in **GvHD** of the lung, compassionate use trial	ongoing/Marketed
Taxotere	Subinvestigator for NSCLC study PhIII	Marketed
Gemzar	Investigator for NSCLC study Ph III	Marketed
Gemzar	Subinvestigator for ovarian cancer study PhIII	Marketed
Gemzar	Subinvestigator for pancreatic cancer study Ph III	Marketed
Rituximab+ 2-CdA	low grade NHL and mantle cell lymphoma	Marketed
Cyclosporine	Ph II trial principal investigator initiated in GvHD of the lung, compassionate use trial	ongoing/Marketed
Ibandronate-Bisphosponate	Subinvestigator Ph II trial hypercalcemia	Marketed
Herceptin	Subinvestigator for breast cancer Ph III	Marketed
Hyperthermia	extracorporeal whole body hyperthermia in met. Breast cancer	Ongoing

Product	Function	Status
Zenapax	Subinvestigator for leukemia PhII	Ongoing
in vivo confocal laser microscopy	Project manager: detection of melanoma	Ongoing
oxaliplatin/5FU	Project manager: advanced pancreatic cancer PhIII with VTE prophylaxis	Ongoing
VTE prophylaxis in solid tumors	Assoc. dir: registry	Ongoing
Long-term VTE prophylaxis combined with Oxaliplatin+ 5FU/FA	Assoc. dir: Ph II trial in pancreatic cancer	Ongoing
Long-term VTE prophylaxis combined with Estramustin	Assoc. dir.: Ph II trial in prostate cancer	ongoing
Selectikine (Immunocytokine)	Consulting medical leader in Ph I trials in cancer	ongoing

Employment History:

Matrix 24 Labs/Eversafe May 2016
started as director of medical department, promoted Oct 2016 to
Chief Medical Officer: design, plan, conduct trial program in malaria and Zika prevention, assist sales in questions regarding product

Consulting, since 2013 LC Cell- EU stem cell regulatory consulting;
Peaklab- performed extensive physical examinations for sports stars;
SDL services- protocol summaries etc.;
GLG council CardioV project
WebMD: German project

Principal Consultant (VP), PAREXEL International
2009 to 2012

- FDA approvals: Wrote 3 CDPs (long-acting G-CSF product including trials in NHL & breast cancer, combination anti-hypertensive drug for 505 (b) (2) NDA-submission. Reviewed numerous NDA- (re-)submissions, successful NDA-submission (wrote 2.7.4 and REMS program, and reviewed 2.7.3, 2.5, 2.2, label, pediatric plan, narratives)), strategy for novel multikinase inh. in CLL, and advised BLA re-submission, reviewed 510k submission
- Wrote global strategy plan for combination product as well as novel mab for breast cancer expert in Regulatory strategy, and global clinical development from phase I-PMS, from strategic planning to GCP operations, and in writing publications and regulatory annual reports, ***IND***, NDA, PMA submissions to FDA and European regulatory authorities
- Assisted PXL's clinical trials group, acted as liaison between trials team and regulatory
- reviewed PSURS, 120 day safety update

Consultant Medical leader at Merck, Germany in the global Clinical Development Unit, Oncology, 2008 to 2009

- Wrote Ph I protocol for an *Immunocytokine* in lung cancer.
- Updated IBs, Questions from Ethics committee, clinical global strategy plan, edited abstract for AACR

Guidant, Cardiovascular Medical Device Company, Global Clinical Science Dept., SF Bay Area, California, January 2006 to September 2007

- Principal clinical scientist
- Responsible for 5 major visibility projects. One especially challenging exploratory early phase project to explore IVUS to predict events in coronary lesions
- Wrote 1 report for 510k and PMA submission to FDA (integrated efficacy and safety report); conducted data analysis for 1 epidemiologic study; was the clinical responsible for 1 *IDE stage product with many preclinical issues providing medical expertise* and wrote strategy document; directed 1 launch-related post-marketing trial.
- I built the clinical affairs dept. from the ground up for new launch

OCOG, a CRO of Keryx Pharmaceuticals, December 2005

Consultant medical writer: wrote 2 abstracts on a Ph II trial results of Abraxane in breast and lung cancer patients

Y's Therapeutics, Burlingame, California, December 2004 – December 2005 (>1 yr)

- Clinical scientist, the only clinical person in Dept. of Clinical Affairs and Regulatory (Oncology, anti-inflammatory/*autoimmune*)
- fulfilling Director duties, reporting to COO, CEO and CBO/President.
  Developing clinical development plans including regulatory strategy for 2 antibodies (cancer, transplantation), orphan filing, hired people and mentored them in the process of drug development
  I led two antibody projects in the development and made major progress. Team members comprised an extensive network of CROs and internal members who were located in US, Europe and Japan. Resolved major issues in clinical design for the projects. Activities included pre-IND meeting and IND studies.
  In-licensing: responsible for identification, evaluation, due diligence with preclinical scientists and CMC.
  I managed Clinical operation, pharmacovigilance and regulatory writing, I later became Co-Medical monitor for 4 clinical trials (2 Ph II of small molecules anti-inflammatory TA (asthma, rA, interstitial cystitis), and 2 antibodies (1 PhI/II in transplantation and other ind., the other ab at pre-IND stage for hem/onc.) assisted in successful IND as well as orphan application and presentation for venture capital group for IPO, wrote safety surveillance plan

Aventis Pharmaceuticals, Germany, 2002 to 2004 (3 yrs)

Medical Advisor in Cardiovascular Medical affairs dept.

- Functioned as Medical monitor and Project Manager of global (US) studies and local studies Phase 2-4, PMS and registries, working on studies from planning phase to evaluation (preparation of final protocols and Case Report Forms, study manuals, management of investigative sites, management of study budgets), EC/IRB application.

- Functioned as Pharmacovigilance advisor, regulatory report writer, wrote/edited multiple publications/study reports etc., and functioned as health economics advisor).
- working in the Cardiovascular/Thrombosis therapeutic area. In detail: she managed 21 trials in 3 years at Aventis from design, protocol writing to publication) 2 global FDA-NDA studies with Lovenox (anticoagulation) for new indication and a new anti-Xa inhibitor for NDA and she functioned as back-up for multiple other Ph III trials.

Hospital Nordwest, Frankfurt, 2001
Residency (inpatients solid tumors, Dr. Hester functioned as subinvestigator in multiple clinical hem/oncology studies including Rituximab, breast cancer.
Internal Medicine- Oncology, Teaching Hospital
German Clinic for Diagnostics, Wiesbaden, 2000- 2001
Residency- ***internship AiP*** in bone marrow transplant unit (outpatient, inpatient service, initiation of a clinical study with inhalative cyclosporine in GvHD; due to the nature of these sensitive patients Dr. Hester interfaced with dept. of intensive care, infectiology, neurology

Memorial Sloan Kettering Cancer Center, NY, 1999-2000
Clinical research Fellow, Department of Medicine, Dermatology clinic (protocol design, IRB submission, poster presentation in Chicago- Dr. Hester was responsible for a medical device trial of in vivo confocal laser scanning microscopy in melanoma and in other skin lesions; She was involved in workgroup meetings on melanoma with dept. heads as well as Cornell University.

Education:
Regulatory Association for Professionals in Regulatory affairs **RAPS academy**: RAC certificate for US-FDA regulations, June 2010

Institut Prof. Braunschweig, Cologne, Germany
Dipl. Health Economist, August 2001-February 2002

Fachkunde/Certificate of Emergency Medicine- Dr.Hester is certified to ride ambulances for serious cases that require physician immediate action

PhD thesis (Immunology) on the Hepatitis G virus: Prospective transfusion study on GBV-C/HGV Flavivirus regarding prevalence in blood donors and in recipients regarding transmission, course of PCR positivity, antibody formation, liver function tests and viral sequence changes.
Free University Berlin, Germany
M.D./Ph.D. May 1999

Publications:
Haas S, Hach-Wunderle V, Mader FH, Paar WD, Hester Katherine **"**An evaluation of venous thromboembolic risk in acutely ill medical patients immobilized at home: the AT-HOME study**"** Clinical Applied Thrombosis and Hemostasis 2007; 13, No. 1, 7-13

Hach-Wunderle V, Mader F, Ruster K, Paar W: An evaluation of venous thromboembolic risk in acutely ill medical patients immobilized at home: the AT-HOME Study.https://doi.org/10.1177/1076029606296392

Darius H, Hester K, Paar WD, Sanderink GJ. Antithrombotische Therapie mit niedermolekularen Heparinen bei Niereninsuffizienz. J Kardiol. 2004;11(7-8):313–316.
Hesselschwerdt HJ, Paar WD, Schellong S, von Hanstein KL. **"**Rates of proximal deep vein thrombosis as assessed by compression ultrasonography in patients receiving prolonged thromboprophylaxis with low molecular weight heparin after major orthopedic surgery**"** Thromb Haemost. 2005;94:532-6 -Dr. Hester wrote parts of it and executed the whole project).
Paar WD, Hester K, Schellong S, von Hanstein KL. **"**Frequency of proximal deep vein thromboses in orthopedic rehabilitation after orthopedic high risk surgery - multicenter sonographic cohort trial**"** Abstract at German society of orthopedics, Berlin, 2004 (Dr. Hester wrote it)
Paar WD, Hester Katherine, Schinzel H, **"**Pharmacokinetics of LMW heparin in renal insufficiency**"** J Kardiol 2004;11 (7-8): 313-16 (Dr. Hester wrote the whole article)
Antonescu CR, Gonzalez S, Halpern AC, Busam KJ, Hester K, Charles C, Sachs DL, ,. "Detection of clinically amelanotic *malignant melanoma* and assessment of its margins by in vivo confocal scanning laser microscopy" Arch Dermatol 2001 Jul;137(7):923-9 - 2001

Busam K,Hester K, Charles C, Halpern AC:
"**Detection of clinically amelanotic malignant melanoma and assessment of its margins by in vivo confocal scanning microscopy"** Arch Dermatol 2001 Aug; 137(7):923-9
Antonescu CR, Gonzalez S, Halpern AC Hester K, Busam K, Sachs DL, "In vivo confocal microscopy in melanocytic lesions-poster presentation" Society of Investigative Dermatology Conference Chicago, IL - 2000
Hester K, Loewenstein E. Lichen "sclerosus et atrophicus case report", presented at Gr. NY Derm. Society, Mount Sinai, NY - Nov 1999

I.Bozze (Saffe): 3 cirrosi 19, T.Berg, (Hester, Katherine,author of entire chapter) Publication of part of my thesis as a book chapter in: "Epidemiology and clinical relevance of newly developed hepatitis-associated viruses"