

CURRICULUM VITAE

Name: Frederick Herman Hausheer, M.D., F.A.C.P.

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SUMMARY:

Dr. Frederick (Fred) Hausheer is a physician-scientist with over 38 years of executive leadership and management experience in US and international (EU, JP, China, others) commercial pharmaceutical research and development (Phase I-III), preclinical translational and clinical medicine, clinical pharmacology, ICH GCP compliance and commercial development strategy and risk management of novel cancer therapeutics. His commercial research and development experience includes cytotoxic agents, targeted agents, immuno-oncology therapeutics, cell therapies (BMT, CAR-T), and supportive care medicines. He is an inventor/co-inventor on more than 400 issued United States and international pharmaceutical patents, and author/co-author of more than 200 scientific/medical publications. He is an experienced former CEO and Chief Medical Officer with several biopharma companies. He is a former NCI-Designated Clinical Investigator, NCI-Institutional Review Board voting member, and NCI-Experimental Therapeutics Section member, and an ad hoc external expert medical advisor for the US FDA. Some of his major awards include the American Cancer Society Fellowship Awards, the National Scientific Research Award, and the Smithsonian-ComputerWorld Award for Breakthrough Science in Medicine. Prior Board Certifications in Internal Medicine and Medical Oncology. He received MD degree from the University of Missouri-Columbia and completed Fellowship in Medical Oncology at the Johns Hopkins Hospital and the Johns Hopkins Oncology Center where his oncology training was focused on development and clinical pharmacology of investigational anticancer therapeutic agents in the Experimental Therapeutics and Pharmacology division at Johns Hopkins. His undergraduate degree is in Biology from Graceland University and graduate degree is in Physiology and Biophysics from the University of Illinois, Champaign-Urbana.

EDUCATION AND TRAINING:

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| 1985-1987 | Senior Clinical Fellow in Medical Oncology
Pharmacology & Experimental Therapeutics Division
(Completed Fellowship & Board Certification in 2.5 years; promoted to Faculty)
The Johns Hopkins Oncology Center & The Johns Hopkins Hospital
Baltimore, Maryland |
| 1983-1985 | Resident, Internal Medicine
University of Missouri-Columbia Hospitals and Clinics
Columbia, Missouri |
| 1982-1983 | Intern, Internal Medicine
University of Missouri-Columbia Hospitals and Clinics
Columbia, Missouri |
| 1979-1982 | M.D., (tested out of 1 st year medical school & graduated in 3 years with Honors)
University of Missouri - Columbia School of Medicine
Columbia, Missouri |

EDUCATION AND TRAINING (CONTINUED):

1977-1979	M.S., Physiology and Biophysics (Academic Scholarship) University of Illinois-Champaign Champaign-Urbana, Illinois
1973-1977	B.S., Biology (Music Scholarship) Graceland University Lamoni, Iowa

CERTIFICATIONS:

National Cancer Institute
Designated Clinical Investigator
Registration Number

#20771 (inactive)

DEA Registration Number

FH1234385 (inactive)

1982 - 2019	License to Practice Medicine (inactive) State of Missouri - License# 2008026261
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1987- 2019	License to Practice Medicine (inactive) State of Maryland - License# D0032301
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1987-2019	Medical Oncology (Board Certified, inactive) American Board of Internal Medicine
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1985-2019	Internal Medicine (Board Certified, inactive) American Board of Internal Medicine
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1983	Diplomate Part III National Board of Medical Examiners
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1982	Diplomate Part II National Board of Medical Examiners
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1981	Diplomate Part I National Board of Medical Examiners
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EMPLOYMENT/EDUCATION/ACADEMIC APPOINTMENTS:

2022-Present	Founder & Managing Partner Hausheer BioMed (USA), LLC Translational Medicine & Global Commercial Oncology Development
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2020-2022	Global Chief Medical Officer Lepu Biopharma, Inc. Shanghai, China & Austin, Texas, United States
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EMPLOYMENT/EDUCATION/ACADEMIC APPOINTMENTS (CONTINUED):

2019-2020	Global Chief Medical Officer & Corporate Senior Vice President WuXi AppTec, Inc. Austin, Texas, United States & Shanghai, China
2018-2019	Interim Chief Medical Officer (Portfolio) Alpha BioPharma, Ltd Shanghai, China
2018-2019	Venture General Partner LYZZ Capital Shanghai, China
2017-2018	Chief Medical Officer Amunix Operating Inc. Mountain View, California
2015 – 2016	Chief Medical Officer & Senior Vice President Medical Sciences InClin, Inc. San Mateo, California
1992- 2015	Founder, Chairman of the Board, Chief Executive Officer & President BioNumerik Pharmaceuticals, Inc. San Antonio, Texas
2008-2022	Clinical Professor of Medicine and Medical Oncology (Adjunct) Department of Internal Medicine University of Missouri-Columbia Columbia, Missouri
2004-2013	Professor Graduate Pharmacology Program Department of Pharmacology University of Texas Health Sciences Center San Antonio, Texas
1996-2020	Professor, Medical Oncology (Adjunct) Department of Pharmacology & Experimental Therapeutics The Johns Hopkins Oncology Center and School of Medicine Baltimore, Maryland
1992-1995	Assistant Professor of Medical Oncology and Medicine (Adjunct) Department of Medicine The University of Texas Health Sciences Center San Antonio, Texas

EMPLOYMENT/EDUCATION/ACADEMIC APPOINTMENTS (CONTINUED):

1991-1992 Associate Director
Institute for Drug Development
San Antonio, Texas

1988-1992 Chief
Molecular Design Laboratory
Cancer Therapy and Research Center
San Antonio, Texas

1988-1992 Assistant Professor of Oncology and Medicine
Department of Medicine
The University of Texas Health
Sciences Center at San Antonio, Texas

1988-1992 Assistant Professor of Oncology (Adjunct),
Experimental Therapeutics & Pharmacology
The Johns Hopkins Oncology Center and School of Medicine
Baltimore, Maryland

1987-1989 Senior Scientist
The Advanced Scientific Computing Laboratory
The National Cancer Institute
Frederick Cancer Research Facility
Frederick, Maryland

1987-1988 Instructor
Medical Oncology, Experimental Therapeutics & Pharmacology
The Johns Hopkins Oncology Center
Baltimore, Maryland

1985-1988 Clinical Preceptor in Medicine
The Johns Hopkins School of Medicine
Baltimore, Maryland

1986-1987 Scientist/Expert
The Advanced Scientific Computing Laboratory
The National Cancer Institute
Frederick Cancer Research Facility
Frederick, Maryland

1979-1983 Lecturer in Medical Pathology
University of Missouri-Columbia
Columbia, Missouri

PRIOR AND CURRENT AFFILIATIONS:

Fellow
American College of Physicians

American Association for Cancer Research

American Society of Clinical Oncology

COMMITTEES AND BOARDS

Present	Member, Global Advisory Committee (representing the United States) HALO (High Performance Computing & Artificial Intelligence Leadership Organization); an independent global organization Medicine and Pharmaceutical Research & Development
2024 - Present	Advisory Council Member Commercial Pharmaceutical/Biotechnology Research & Development Harvard Business Review
2009- 2017	Research & Development Advisory Board University of Missouri-Columbia Columbia, Missouri
2000 - 2008	Business Advisory Board (Pharmaceuticals & Biotechnology) J.P. Morgan Chase Manhattan Bank San Antonio, Texas
2000 -2001	Member Advisory Board Expert Panel High Performance Computing – Pharmaceutical/Biotechnology RCI
2001-2015	Advisory Council The Whitaker Biomedical Engineering Institute The Johns Hopkins University
1997-2007	Trustee The Medical School Foundation University of Missouri-Columbia School of Medicine
1998- 2001	Judge Medicine The Smithsonian Computerworld Awards
1997 - 2001	Scientific Advisory Board Member Susan G. Komen Breast Cancer Foundation San Antonio, Texas

COMMITTEES AND BOARDS (CONTINUED):

1996 - 2004	Board Member Continuing Medical Education Drug Information Association
1991-1998	Voting Member (Peer-Reviewed by National Appointment) Experimental Therapeutics Study Section I The National Cancer Institute
1992 - 1995	Scientific Advisor and Member Pharmaceutical Research and Development Executive Board International Business Machines (IBM) Corporation
1992	Chairman BioMedical Research Supercomputing Supercomputing '92
1989 - 1994	Expert Scientific Reviewer: Cancer Treatment Research The National Science Foundation (NSF)
1990 - 1992	Chairman, NCI Decision Network Panel, Antisense DNA therapeutics Translational Medicine and Clinical Oncology Development The National Cancer Institute
1989-1991	Expert Medical Reviewer Texas State Medical Board
1987-1988	Institutional Review Board Member Medical Oncology (NCI-Sponsored National Trials) The National Cancer Institute Frederick Cancer Research Facility Frederick, Maryland
1987-1988	<i>Ad Hoc</i> External Expert Oncology Medical Reviewer/Advisor United States Food and Drug Administration (FDA)

HONORS AND AWARDS:

1997	Recipient Smithsonian – Computerworld Leadership Award in Medicine Breakthrough Computational Science Mechanism-Based Drug Discovery The Smithsonian Institute and Computerworld
1997	Recipient Outstanding Young Physician Award The University of Missouri-Columbia School of Medicine

HONORS AND AWARDS (CONTINUED):

1995	Recipient 40 under 40 San Antonio Business Journal
1994, 1995 & 1996	Medicine Awards The Smithsonian – Computerworld Awards The Smithsonian Institute and Computerworld
1992	Recipient The Forefronts of Large-Scale Computation Award Computational Drug Design in Oncology & HIV Drug Discovery & Development Supercomputing 1992 IEEE International Supercomputing Society
1992-1995	Physician's Recognition Awards (consecutive years) American Medical Association
1992	Cray Research Award (2 concurrent Awards) Supercomputer Guided Drug Design
1991	Cray Research Award (2 concurrent Awards) Supercomputer Guided Drug Design
1990	Cray Research Award Supercomputer Guided Drug Design
1989	Cray Research Award Supercomputer Guided Drug Design
1988-1992	Research Fellow Center for High Performance Computing The University of Texas
1989-1992	Physician's Recognition Awards (consecutive years) American Medical Association
1986-1987	National Scientific Research Award The Johns Hopkins Oncology Center
1985-1988	Physician's Recognition Awards (consecutive years) American Medical Association
1985 & 1986	Recipient, American Cancer Society Clinical Fellowship Award The Johns Hopkins Oncology Center

HONORS AND AWARDS (CONTINUED):

1970 & 1971 Eagle Scout Award (age 14)
God and Country Award (age 15)
Member of Eagle Court of Honor Guard
Ewing M. Kaufmann Eagle Scout Court of Honor
Kansas City, Missouri

JOURNAL REVIEWER:

1988 Investigational New Drugs

1989 Cancer Research

1991 Journal of the American Chemical Society

1991 Biopolymers

1992 IEEE-Computer

1993 Journal of Physical Chemistry

1994 Current Drugs

2000 Cancer Chemotherapy and Pharmacology

BUSINESS EXPERIENCE AND INTERESTS:

More than 35 years of experience in founding, building, financing, structuring and leading two private internationally operated oncology pharmaceutical research and development organizations. Extensive experience in the leadership and management of clinical, non-clinical, regulatory and commercial operations essential for global oncology drug development. More than 35 years of combined experience in oncology drug discovery research, translational medicine, global commercial oncology drug development and pharmacology.

BUSINESS EXPERIENCE AND INTERESTS (CONTINUED):

Career Goals: To make tangible contributions to the discovery and efficient global development of safe and more efficacious new drugs for patients with cancer and other serious diseases. Constructively engaged in the leadership and management of a leading research and development organization for cancer therapeutics by helping to discover, develop and internationally commercialize innovative new oncology drugs.

Corporate Alliances and Partnerships: Architected and implemented strategic alliances and corporate relationships with the Johns Hopkins Oncology Center, UCLA biomedical and research institutions directed by the Board of Regents, Cray Research, IBM, Roswell Park Cancer Institute, Southwest Foundation for BioMedical Research, Lawrence Livermore National Laboratory, Bristol-Myers Squibb, Grelan Pharmaceuticals, a co-founder and Chairman of a joint venture KI Pharma/ASKA Pharmaceuticals in Japan, and strategic alliances with Baxter Oncology in Europe (formerly ASTA Medica Oncology) and Takeda Pharmaceuticals (involving separate alliances in the United States and Japan).

Corporate Finance: Led private financing transactions for the Company through private equity placements and stock purchases, as well as structuring and negotiation of pharmaceutical strategic alliances totaling in excess of \$500 MM in aggregate financial term commitments. Led and managed procurement of more than \$250 MM in capital for funding of operations. Led the development and instillation of strong corporate financial discipline and effectiveness as a part of the corporate culture along with effective financial operations and procedures. Have served as a key advisor and/or partner in due diligence of technologies/assets and companies for acquisitions, mergers, investments in the Pharma/Biotech sector for over 30 years.

Operations, Thought Leaders and Facilities: Established and implemented U.S. and foreign (global) Phase I-III clinical trials operations for oncology drug development. Experienced in the design, implementation, conduct, execution and successful completion of Phase I, Phase II and Phase III oncology clinical trials in the U.S., China, Japan, Europe and ROW. Established an international oncology thought leader network in the U.S., Japan and Europe, and implemented operating and quality procedures for clinical trials. Planned and implemented the construction and equipping of a high-performance computing facility (5,000 square feet; more than 0.8 TeraFLOP and 25 TByte aggregate 24/7 operating computing capacity), and fully instrumented compliant pharmaceutical research laboratories (15,000 square feet) for synthetic chemistry, analytical chemistry, biology, drug formulation, pilot plant cGMP drug product manufacture, and molecular pharmacology research.

Company Boards and Employees:

Identified and recruited highly qualified and experienced independent members to serve on the Company Board of Directors. Identified and recruited internationally recognized cancer drug and scientific experts to Scientific Advisory Boards.

Management and Operations: Structured and managed the formation and build out of Company research and business operations in therapeutic focus and product development areas including drug discovery, computational methods and applications, chemistry, biology, pharmacology, toxicology, regulatory affairs, patents and intellectual property, clinical development and strategy, cGMP operations, personnel and facilities, GCP operations, finance, legal, banking and accounting for the Company.

Corporate Culture: Developed and implemented a strong cooperative execution-focused corporate culture for pharmaceutical research and development operations that foster multidisciplinary teamwork, effective communication, creativity and the opportunity for every employee to contribute, learn and grow professionally. Our primary objective has been to identify, build, match and optimize the strengths of people in our company with the organizational structure in order to maximize effectiveness through multidisciplinary teamwork in scientific and business problem solving and execution.

PHARMACEUTICAL RESEARCH & CLINICAL ONCOLOGY DRUG DEVELOPMENT EXPERIENCE

Experienced in the formulation, design, implementation and execution of clinical and non-clinical drug development and approval strategies for NCE and biosimilar oncology drugs in the U.S., China, Eastern and Western Europe, S. Korea, Taiwan, Australia, Singapore and Central/South America/Canada.

Leadership and management experience in the formulation, design, implementation, and execution of global oncology clinical drug development strategies, including the design and conduct of clinical trials, the requisite data management and statistical requirements, presentations and negotiations with regulatory authorities in the U.S., Europe, China, Korea, Taiwan, Japan, Australia and New Zealand. Extensive leadership experience in presentations, discussions and communications with the FDA, EMA, PMDA, NMPA, MFDS, and other regulatory agencies.

Past experience as a practicing medical oncologist, NCI-designated clinical investigator and board-certified internist/medical oncologist provided a patient care and physician/scientist commercial research and development perspective on clinical oncology drug development and the formulation of strategies for drug development and approval.

Professional interactions with international oncology thought leaders and oncology experts, cooperative groups including CALGB, ECOG, SWOG, the NCI, Compendia (e.g., United States Pharmacopeia) and support groups for commercial development of oncology products. This network has been built by many years of professional experience in the field of oncology developmental therapeutics and research.

Professional experience in the design, preparation and implementation of clinical and non-clinical studies and protocols, investigator's brochure, INDs, and coordinating to meet regulatory and drug supply requirements, implementation and execution of all phases of oncology and a variety of non-oncology clinical trials in the U.S., China, Europe, Japan and ROW. Extensive direct involvement in the design and conduct of NCE and biosimilar oncology clinical trials, directly involved in FDA, NMPA (formerly CFDA), PMDA, EMEA, MFDS (S. Korea) and other foreign regulatory agency interactions/discussions – for oncology IND/Phase I through Phase III oncology development programs. Leadership, management and operating experience in essential operations to coordinate for effective drug development in oncology; clinical, cGCP, cGMP (safety and compliance), regulatory, non-clinical studies, and in building and coordinating effective global multidisciplinary research and development teams.

DUE DILIGENCE AND INVESTMENTS, ACQUISITIONS

Over 30 years of experience in due diligence for investments, licensing, mergers, acquisitions for institutional investors, private equity, Angel investors, and investment banks in the biotechnology, pharmaceutical, medical device, and diagnostic testing industry sectors. In the past 8 years I have been extensively working in China and US focused in terms of assets and commercial preclinical and clinical development, and as a Venture Partner and in Corporate Investments as well as working with various venture capital firms, reviewing as many as 10-15 assets per week for investment for LYZZ Capital, WuXi AppTec Corporate and 6 Dimensions Capital, as well as consulting biotech and other venture firms I have been involved in the scientific, medical, and commercial development risk assessment and review of more than 100 potential investment programs per year (2018-2022).

TRANSLATIONAL (NON-CLINICAL AND CLINICAL) RESEARCH MANAGEMENT EXPERIENCE

Extensive experience in the human-relevant physiological design and oversight of non-clinical GLP and non-GLP studies involving numerous different investigational oncology medicaments for regulatory purposes in a wide variety of relevant animal species and human/non-human tumor/transformed and transgene inserted cell lines involving toxicology, pharmacokinetics, antitumor efficacy, oral/iv bioavailability, metabolism, ADME, dose finding, protein binding, hERG and cardiac toxicity, and others. Extensive management experience in translational research analysis and design and have provided scientific/strategic contributions in our research and development operations for eight drug discovery areas and ongoing clinical drug development operations. Experienced in the design and optimization of experiments using multiple simultaneous variable statistical methodology. Have invented and developed several novel pharmaceutically elegant, patented formulations of highly insoluble drugs including taxanes, camptothecins and others; experienced in preformulation and formulation research and required regulatory testing for parenteral and oral formulations of drugs.

Experienced in the operations and requirements for discovery, translational commercial research and development and pharmacology of new drugs for treatment of cancer and related toxicities. Prior medical and research development experience and training have been applied through direct involvement and contribution in the development and implementation of technology for drug discovery and development using advanced physics-based computing, including proprietary software development and as well as medical oncology, drug development and pharmacology. Major interest in developing and coupling mechanism-based, numerically intensive engineering and optimization methods to all stages of drug discovery development by the application of advanced physics-based numerical and visual simulation technology to guide and complement multidisciplinary experimental efforts involving chemistry, biology, pharmacology, safety, delivery and drug formulation for the purpose of obtaining a more in depth understanding the mechanisms of action of drug candidates at an earlier stage of development.

Led development and implementation of a fully integrated pharmaceutical discovery and research development capability in house with high performance computing systems, quantitative physics-based numerical simulation methods (commercial and proprietary), chemistry – synthetic, analytical, and pilot GMP capability, biology and molecular pharmacology instrumentation and *in vitro* screening, drug interactions. Led and managed the development of many HPLC LC/MS and fluorescent, single- and dual/multi-detection based analytical pharmacokinetic assay methods for oncology drugs in the last 20+ years and implemented full analytical capability for HPLC with electrochemical, fluorescence, UV, mass spectrometry and ion exchange chromatography capabilities. Implemented high field NMR capability in house which is used routinely to complement many analytical studies for chemistry and biochemical studies.

Expertise in deployment and utilization of a variety of high-performance computer architectures, including parallel high performance computer architectures including vectorization and parallel processing. Expertise in the application and limitations of statistical mechanical methods - including molecular mechanics, molecular dynamics, normal mode analysis, free energy perturbation methods (AMBER and CHARMM), and special interest and experience involving chemical, thermodynamics, reaction profiling and structural applications of GAUSSIAN and SPARTAN series of programs (*ab initio* quantum mechanical programs) and other computational chemistry software programs.

PROPRIETARY SOFTWARE DEVELOPMENT

SCIENTIFIC/TECHNICAL Application architect for the design, development and implementation of a proprietary parallel, *ab initio* quantum mechanical and classical (molecular dynamics) merged program for pharmaceutical research. Developed a novel DNA/RNA triple helical conformational program, and performed the first triple-helical DNA free-energy thermodynamically corrected simulations examining the effect of cytosine methylation and DNA hybridizations using AMBER; this work correctly predicted the existence of DNA triple helices and the greater binding affinity of 5-methyl cytosine which was later experimentally proven. Application architect for the development of proprietary combinatorial chemistry, pharmaceutical formulation algorithms and *SuperFold* – a sophisticated atomic level and physics-based (non-Monte Carlo) proprietary protein and nucleic acid low energy conformation folding program and chemical fragment databases. *Superfold* is a parallel quantum mechanically derived molecular property parameters fitted into a statistical mechanics/molecular dynamics construct that integrates time-dependent free-energy perturbation (state coupling using integrated or window sampling along the perturbation) to generate high probability protein and nucleic acid structures.

CLINICAL TRIALS, CTMS SOFTWARE SYSTEMS: Initiated and led development of a fully integrated proprietary clinical trials software management system and database along with manufacturing supply chain, drug discovery and other modules that allow a proprietary integrated IT application for our business operations. Planned and proposed this strategy from inception to fruition. We have successfully

developed and implemented a proprietary Clinical Trials Management System (CTMS) software; this was licensed and in national use by the Cancer and Leukemia Group B (CALGB), a major U.S. national academic oncology cooperative group. CTMS is an innovative core software technology that allows facile data collection, data processing, HIPAA compliant storage and retrieval of information regarding patients, demographics, treatment, outcomes and their respective health care providers and institutions for U.S. and international clinical trials. We developed business rules and implemented drug product software capability that is integrated with CTMS – a GMP Inventory Tracking System software system was designed and implemented. Also developed a radiological image capture and reporting software program to allow remote review of clinical trial radiological images.

ACADEMIC TEACHING AND TRAINING EXPERIENCE At Johns Hopkins and at UTHSC from 1988-1992, one-month inpatient Phase I Attending per year, General Medical Oncology (2-4 months inpatient Attending per year), and Internal Medicine (one to two months inpatient Attending per year). Responsible for supervision of the Audie Murphy Veteran's Hospital Medical Oncology Outpatient Clinic (1991-1992). During this period extensive participation in Phase I clinical trials and pharmacology studies, and Phase II, Phase III clinical trials, and with bone marrow transplantation (Allogeneic, Autologous, Syngeneic), and the treatment of patients with solid tumors and leukemias.

Teaching: In the past have enjoyed teaching medical House staff and find this a rewarding experience. Was selected as a Clinical Preceptor in Internal Medicine at the Johns Hopkins School of Medicine for teaching Internal Medicine diagnosis and management (1986-89) and was ranked number one as a Medicine Attending Physician in the Department of Medicine by the Medicine House staff in 1991 and ranked in the top 5% as a Medicine Attending by the House staff 1989, 1990, and 1992 at the University of Texas Health Sciences Center.

Ph.D. Thesis Advisor (1990-2008):

1. Doctoral Thesis advisor in *Biophysical Chemistry* to Regina Monaco (*cum laude*) at University of Texas Department of Chemistry 1990-1992.
2. Doctoral Thesis advisor for Anna Marie Van Hattum (*high honors*) in *Pharmacology* at the Free University Hospital in Amsterdam in 1997-2002.
3. Doctoral Thesis advisor and Doctoral Thesis Lead Adjudicator in *Pharmacology* for Miranda Verschraagen (*highest honors*) from 1997-2003 at the Free University Hospital in Amsterdam.
4. Doctoral Thesis advisor, review panel member for Jerry Huang (*cum laude*) in *Medicinal Chemistry* at Temple University in 2001-2004.
5. Doctoral Thesis advisor in *Pharmacology* for Dakshine Shanmugarajah (*cum laude*) at the University of Texas Health Sciences Center; 2004-2008.

Drug Safety, GCP Compliance, Medical Review and Adjudication:

Lead architect for design and implementation of a fully compliant (ICH and 21 CFR Part 11 compliant) Multi-Tenant Enterprise Gold Argus Oracle pharmacovigilance and drug safety capture and reporting system, including validation, work process and SOPs within six months. Included several proprietary implementations that improve quality, turnaround speed, e.g., NCI-CTCAE (current version) severity/grade systems for Adverse Events, including SAEs and AESIs.

Have served as a global medical expert for safety and ICH GCP and Sponsor's designated clinical trial operations and safety management oversight for oncology trials as well as non-oncology studies (infectious disease, allergy) with over 30 years of international developmental drug safety review and reporting experience.

Have served as lead medical expert (internal medicine and medical oncology), and ICH GCP compliance expert opinion for complex multi-national ICH GCP non-compliance including international litigation and arbitration of oncology and non-oncology Phase III clinical trials involving multi-billion-dollar assets and recovery for lost revenue and profits and damages.

Clinical Trials and Protocols: Leadership & Management Accountability, Primary Role in Conception, Design, Preparation, Strategic and Operational Planning, Investigator Recruitment, CRO Selection/Negotiations, Regulatory Discussions and Logistical Support for Commercial IND Development Studies Conducted in the US, China, Europe (and Eastern Europe), Japan, S. Korea, Australia, Taiwan, and Singapore.

Summary of Recent Commercial Drug Development Experience (2016-Present):

Extensive involvement in commercial strategy formulation, clinical trial design, risk-managed commercial development, and regulatory strategy for more than 300 Phase I-III clinical programs involving small, mid and large cap pharma/biotechnology companies in the past 10 years. Therapeutic areas include immuno-oncology (BiTEs, CAR-T, monoclonals, bispecific antibodies, vaccines, antibody-drug conjugates, siRNA/shRNA; NCEs and including biosimilars/bioequivalent generics – eg., CD20, VEGF, HER2, G-CSF, RANKL therapies), biologicals, small molecules (targeted and cytotoxic), CAR-T therapies and bone marrow (autologous and allogeneic) transplantation, and gene therapy, and supportive care investigational products. Territories include US, China, Europe, S. Korea, Taiwan, Japan, Eastern Europe, and Australia/New Zealand.

Typically, I am engaged by Sponsors to help solve or mitigate complex development issues in translational medicine, trial design, risk management, and global commercial development strategic planning for multi-territorial development programs as well as due diligence for acquisition/investment/licensing.

Representative Core Phase I-III Multinational Studies:

Phase I & Pharmacokinetic Studies (Territory)

1. Phase I Trial of Escalating Doses of BNP7787 In Patients with Solid Tumors Undergoing Treatment With Cisplatin and Paclitaxel. United States.
2. Phase I Trial of Escalating Doses of BNP7787 In Patients with Solid Tumors Undergoing Treatment with Cisplatin. Europe. Pharmacokinetics.
3. Phase I Trial in Patients with Relapsed Ovarian Cancer to assess the nephro- and neuroprotective effect of BNP7787 in cisplatin-containing chemotherapy and to assess the pharmacokinetics of carboplatin and paclitaxel in the presence of BNP7787. Europe.
4. Phase I Study of Tavocept in Patients with Non-Small Cell Lung Cancer. Japan. Pharmacokinetics.
5. Phase I Trial of Escalating Doses of Karenitecin Administered Intravenously Daily for Five Consecutive Days In Patients With Advanced Solid Tumors. United States. Pharmacokinetics.
6. Phase I Trial of Escalating Doses of Karenitecin Administered Intravenously Daily for Five Consecutive Days in Pediatric Patients with Refractory or Recurrent Solid Tumors. National Study (POG) United States. Pharmacokinetics.
7. Phase I Evaluation of the Safety of Karenitecin in the Treatment of Recurrent Malignant Gliomas. Pharmacokinetics. National Study (North American Brain Tumor Consortium). United States.
8. Phase I Trial of Oral Karenitecin in Patients with Solid Tumors. United States. Pharmacokinetics.
9. A Phase I Trial of Escalating Doses of Karenitecin™ plus Cyclophosphamide Administered Intravenously Daily for Five Consecutive Days in Pediatric Patients with Refractory or Recurrent Solid Tumors. United States.
10. Phase I Trial of Oral Karenitecin in Patients with Solid Tumors. Europe.

11. Phase I Trial of Escalating Doses of γ -Methylene-10-deazaaminopterin (MDAM) Administered Daily for 5 Consecutive Days in Patients with Advanced Solid Tumors. United States.
12. A Randomized, Single Administration, Double-Blind, Placebo-Controlled Study of Safety, Tolerability, and Pharmacokinetics of Tavocept™ (BNP7787) in Healthy Volunteers. United States.
13. Phase I Study of Karenitecin Administered Daily for 5 Days in Patients with Solid Tumors. Japan. Pharmacokinetics.
14. Phase I Safety and Pharmacokinetic Study of Novel Targeted Agent in Healthy Volunteers. Australia.

Phase II and Adaptive Trials (Territory)

1. A Phase II Randomized Study of Dose-Dense Docetaxel and Cisplatin Every Two Weeks with Pegfilgrastim and Darbapoetin Alpha with and without the Chemoprotector BNP7787 in Patients with Advanced Non-Small Cell Lung Cancer. United States.
2. Phase II Trial of IV Karenitecin (IND 57250) in Patients with Relapsed or Refractory Advanced Non-Small Cell Lung Cancer. National Study (CALGB). United States.
3. Phase II Treatment of Adults with Primary Malignant Glioma with Karenitecin. National Study (North American Brain Tumor Consortium) United States.
4. Phase II Trial of Karenitecin (IND 57,250) in Patients with Malignant Melanoma. United States.
5. A Phase II Evaluation of Karenitecin (IND 57,250) in the Third-Line Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma. National Study (GOG) United States.
6. Phase I/II Trial of Valproic Acid and Karenitecin in Metastatic Malignant Melanoma. United States. Pharmacokinetics.
7. Phase I/II Trial of Oral Karenitecin in Patients with Solid Tumors. United States. Pharmacokinetics.
8. Phase I/II Multi-Cohort Disease (Basket) Adaptive Design for Novel Targeted Agent in Hematologic Malignancies (AML, CML, MDS, MPD). Commercial Sponsor. United States. Pharmacokinetics.
9. Phase II Randomized Multi-National Trial of Novel EGFR TKI +/- Investigator's Choice Care in EGFR mutation+ Advanced NSCLC Patients with Leptomeningeal Metastases. China, S. Korea.
10. Phase I/II Trial of Novel EGFR Inhibitor in NSCLC Patients with CNS Metastases. China. Pharmacokinetics.
11. Phase I/II Trial of Novel HER2 ADC in Patients with Advanced Solid Tumors and Gastric/GEJ Cancers. United States and China. Pharmacokinetics.
12. Phase I/II Trial of Novel Claudin 18.2 Targeting Antibody in Patients with Advanced Solid Tumors and Gastric GEJ Cancers. United States. Pharmacokinetics.
13. Phase I/II Trial of Novel 41BB Agonist in Patients with Advanced Solid Tumors and NSCLC, Melanoma, or Non-Hodgkins's Lymphoma Patients. United States and China. Pharmacokinetics.
14. Phase I/II Trial of Novel TIM3 Agonist with Advanced Solid Tumors and Advanced NSCLC Patients. United States and China. Pharmacokinetics.

Phase III (International, Multicenter)

1. BNP7787 vs. Placebo for Prevention of Paclitaxel Neurotoxicity: A Double-Blind International Randomized Phase III Trial in Patients with Metastatic Breast Cancer. United States, Europe, Russia & Ukraine.
2. BNP7787 vs. Placebo for Prevention of Paclitaxel Neurotoxicity: Phase III Multicenter Randomized Comparative Trial in Patients with Metastatic Breast Cancer. Japan.
3. BNP7787 vs. Placebo for Prevention of Paclitaxel and Cisplatin Neurotoxicity: A Randomized, Double-Blind, Placebo-control, International, Phase III Trial in Patients with Advanced Non-Small Cell Lung Cancer. Europe.
4. BNP7787 vs. Placebo for Prevention of Neurotoxicity: A Randomized Double-Blind, Placebo-Controlled, Multi-center Phase III Trial in Patients with Advanced Non-small Cell Lung Cancer (NSCLC) Receiving Paclitaxel and Cisplatin. Japan.

5. Randomized, International Double-Blind, Phase III Trial of Tavocept versus Placebo in Patients with Newly Diagnosed or Relapsed Advanced (stage IIIB/IV) Primary Adenocarcinoma of the Lung Treated with Docetaxel or Paclitaxel plus Cisplatin. United States, Europe, Russia, Ukraine and Central and South America.
6. Randomized Phase III Study of Safety and Efficacy of Karenitecin Versus Topotecan Given IV for 5 Consecutive days Every 3 Weeks in Patients with Recurrent Advanced Epithelial Ovarian Cancer. United States, Europe and South America.
7. Randomized Phase III Study N-SAS BC 02 in Adjuvant Breast Cancer. National Study. Japan.
8. Randomized International Phase III Immuno-Oncology Trial in Triple Negative Breast Cancer Patients for Commercial Sponsor. US, EU, China, S. Korea, Taiwan, and ROW.
9. Randomized International Phase II/III Study of Novel EGFR TKI vs. Gefitinib/Erlotinib in Advanced NSCLC with Brain Metastases. China, S. Korea.
10. Randomized International Phase III Study of Novel Checkpoint Inhibitors and Agonist (PD-1, LAG3) in Patients with Advanced NSCLC United States, China, Europe, Eastern Europe, S. Korea, Taiwan and Singapore.

Quality of Life Instrument Validation Studies

1. Patient Neurotoxicity Questionnaire (PNQ) validation studies. Two large randomized multicenter Phase III trials in early-stage breast cancer and adjuvant chemotherapy treatment with four neurotoxic regimens. Controlled trial design with physician reported neurotoxicity based on standardized required neurological evaluations compared to patient reported neurotoxicity. Japan.
2. Multicenter Randomized Phase III Study in Breast Cancer. Feasibility and validity of the Patient Neurotoxicity Questionnaire (PNQ) during taxane chemotherapy in a phase III randomized trial in patients with breast cancer: N-SAS BC 02. Japan.
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- U.S. House of Representatives, Washington D.C.
- Hearing on Information Technology for the 21st Century, March 18, 1999 The Presidential Initiative for Technology And Computing (PITAC)
- Witnesses:
 - The Honorable Neal Lane, Assistant to the President of the United States for Science and Technology
 - Frederick Hausheer, MD, FACP, Chairman and CEO, BioNumerik Pharmaceuticals, Inc.
 - Dr. Ken Kennedy, Co-Chair, President's Information Technology Advisory Committee
 - Dr. Erich Bloch, President, Washington Advisory Group, former Science and Technology Advisor to President Reagan, IBM Fellow
 - Dr. Steven Wolff, Executive Director, Cisco Systems
 - Dr. Hal R. Varian, Dean, School of Information Technology, U.C. Berkely

PATENTS AND OTHER INTELLECTUAL PROPERTY

Inventor or co-inventor of more than 400 United States and international patents involving new pharmaceutical compositions of matter, processes, formulations and methods of use for medical conditions and disorders. Inventor or co-inventor and co-developer of more than 100 proprietary computer algorithms and programs for pharmaceutical discovery and development concerning chemical optimization, combinatorial chemical substitution, drug delivery, metabolism, drug formulation, targeting and mechanism of action simulations using integrated quantum and classical thermodynamics and structural methods.

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