JULIE KROP, MD
8 Saint Ronan Terr
New Haven, CT 06511
617-955-5319

PROFILE

Creative, strategic physician-leader with a breadth of development experience across multiple therapeutic and orphan indications in the biopharmaceutical industry. Prior roles include senior leadership positions across Clinical Development, Regulatory Affairs, and Medical Affairs in large pharma as well as medium and small sized biotech companies. Extensive experience in early and late-stage development of both orphan and non-orphan drug candidates through approval and post-approval life cycle management. Strong regulatory background including leading pre-IND meetings, EOP2 meetings, US and EMEA filings for approval, and FDA advisory panels. Unique combination of strong technical skills with a strategic, practical, and entrepreneurial focus on successfully driving a business forward.

PROFESSIONAL EXPERIENCE

Aquestive Therapeutics (NASDAQ AQST)

Board of Directors; Feb 2021- present

Beth Israel Deaconess Cancer Center

Advisory Board May 2023- present

FDA Pulmonary/Allergy Drugs Advisory Committee Feb 2024- present

Industry Representative

PureTech Health

Chief Medical Officer and Head of Development, October 2021- present

- Member of Executive Leadership Team
- Lead a fully integrated development organization including Translational Medicine, Clinical Development, Regulatory Affairs, Medical Affairs, Pharmacovigilance, CMC, Program Management and Clinical Operations for multiple clinical stage programs:
    - Built cross functional team from 5 people to approx. 30
    - Ongoing Phase 2b IPF study, Phase 2a AML and Head and Neck I/O study, and multiple early-stage programs (2 Phase 1 and 3 pre-clinical) with novel drug delivery platform that enables drugs to be absorbed directly into the lymphatics and bypass first pass metabolism in the liver allowing oral administration of drugs that previously required IV delivery.

Freeline Therapeutics

Chief Medical Officer April 2020-October 2021

- Member of Executive Leadership Team
- Led and built a fully integrated development organization including Clinical, Regulatory, Medical Affairs, PV, and Clinical Operations; responsible for building out US operations
- Responsible for 3 Clinical Stage gene therapy programs
- Key participant in successful IPO 8/2020 raising over 200 million dollars

AMAG Pharmaceuticals

Chief Medical Officer, Executive Vice President, Development 2015 -March 2020
Chief Medical Officer, Senior Vice President, Clinical Development & Regulatory Affairs 2015-2017

- Member of Executive Leadership Committee
- Oversaw entire Development organization (70+) consisting of clinical development, regulatory affairs, clinical operations, program management, statistics, medical writing, medical affairs, and pharmacovigilance
- Primary clinical spokesperson — media, investor relations

Regulatory/Clinical Development Accomplishments at AMAG:

- Built up development and medical affairs functions from 6 people to 70+
- sNDA approval of Feraheme for iron deficiency anemia
- sNDA approval of Makena SC Autoinjector, orphan drug to reduce the rate of pre-term birth in women with a prior pre-term birth
- NDA approval of Vylessi, a novel MC4 agonist for treatment of hyposexual desire disorder
- Ciraparantag, obtained fast track status for the reversal of factor Xa inhibitors in a patient with a severe bleed or requiring urgent surgery- asset phase 2b ready
- DIF, orphan drug for treatment of severe pre-eclampsia in phase 2b/3a
- Presenter and moderator for FDA Advisory committee meeting for Makena

Vertex Pharmaceuticals 2012-2015

Internal Medicine Development Lead, Vice President, Clinical Development 2014-2015

- Responsible for all early and late-stage development programs for all non-CF programs in the

company

- Designed and led successful POC for VX-150 pain program
- Designed and lead Spinal cord injury program for novel therapeutic
- Partnered with Research group to build development plans for all early stage compounds in the portfolio
- Lead clinical evaluation of all external business development assets under consideration
- Reported directly to the CMO and Head of development

Development Team Lead for HCV Franchise, Vice-President, Clinical Development 2012-2014

- Provided overall leadership and strategic direction for all aspects of development (clinical, regulatory, CMC, toxicology, medical affairs) within the Hepatitis C disease area reporting directly to the Executive leadership team. Worked closely with Commercial Lead for HCV to align on strategy for all aspects of the business franchise
- Primary liaison for all external Hepatitis C partnerships
- Oversaw all project development teams related to HCV
- Responsibility for all post-marketing strategies and post approval commitment studies
- Evaluated all external business development opportunities for the franchise

Stryker Regenerative Medicine, Hopkinton, MA 2006-2012

Vice-President, Clinical Development and Regulatory Affairs

- Member of the executive leadership team and played an integral role in the overall strategic business plan of the division.
- Responsible for providing overall leadership and strategic development for all Clinical and Regulatory activities in the company including assisting in preclinical efficacy and safety studies, IND preparation, clinical trial design and protocol development, management of conduct of trials, and regulatory strategy and execution for product approvals.
- Obtained EMEA approval of BMP-7 for spinal fusion surgery and led FDA Advisory Panel Meeting for approval in US
- Successfully advanced drug candidates from IND through a phase 2 proof of concept study in osteoarthritis and degenerative disk disease.

Peptimmune, Cambridge, MA 2003-2006

Vice-President of Clinical Development

- Member of the executive leadership team.
- Responsibility for all aspects of clinical development and clinical operations for the company. Oversaw phase 1 and phase 2 clinical studies in obesity, MS, and pemphigus vulgaris (orphan drug designation).
- Key participant in raising capital for the company as well as business development discussions with potential large pharmaceutical partners.

Millennium Pharmaceuticals, Cambridge, MA 2001-2003

Senior Director, Clinical Research for Metabolic Diseases and Inflammation

- Oversaw pre-clinical and early clinical programs for Millennium/Abbott metabolic collaboration.
- Designed and completed successful Phase 2b proof of concept study evaluating MLN-02 for ulcerative colitis and Crohn's Disease that was ultimately approved by FDA. (Entyvio)
- Oversaw committee to establish processes to improve all aspects of clinical trial data collection and analysis for the entire clinical organization.

Pfizer Pharmaceuticals, Central Research, Groton, CT 1999-2001

Associate Director, Clinical Research

- Oversaw two phase 3 trials for Inhaled Insulin
- In charge of the pulmonary safety strategy for the compound; designed large safety cohort study to address potential changes in pulmonary function over time.
- Clinical representative for joint development/strategic oversight committee with collaboration partner, Aventis.

Johns Hopkins University School of Medicine, Baltimore, MD 1997-1999

Instructor, Faculty member

- Department of Medicine, Division of Endocrinology.
- Co-PI on several endocrine- related clinical trials.

EDUCATION

Brown University, 8-Year Program in Liberal Medical Education, BA with honors, 1990

Brown University School of Medicine, MD. Graduated with high honors. 1993

Georgetown University Hospital, Resident, Department of Medicine.

Johns Hopkins School of Medicine, Fellow, Department of Endocrinology.

Robert Wood Johnson Clinical Scholars Program, Johns Hopkins University School of Medicine. Selective two-year fellowship in epidemiology and clinical trial design, execution, and statistical analysis.

Harvard Business School Executive Management Program

Academic Honors

American College of Physicians Scholarship for Internal Medicine

American Medical Women's Association- Janet Glasgow memorial Achievement award for academic Excellence

Society of Sigma Xi

ACADEMIC EXPERIENCE

Johns Hopkins School of Medicine, Department of Endocrinology

Participated in curriculum development and teaching of core curriculum in endocrinology for house staff and medical students.

Johns Hopkins University School of Medicine
Group leader for diabetes section of medical school pathophysiology course

Johns Hopkins School of Medicine Admissions Committee

Member of Medical School Admissions- Johns Hopkins School of Medicine.

BOARD CERTIFICATION/PROFESSIONAL COMMITTEES

Diplomate, American Board of Internal Medicine, Board certified in Endocrinology
Member of Endocrine Society
Member of The Boston Club (executive woman's organization)
Member Healthcare Businesswomen's Association

Steering Committee, Boston CMO Network
Co- Chair and Moderator for 6th and 7th Annual Chief Medical Officer Summit, May 2018/April 2019
HBA invited speaker "Navigating a Path to the C-Suite" June 2018 Speaker
Member of HBA executive Woman's Forum in Boston
Selected to participate in Woman in Bio's Boardroom Ready Program

PUBLICATIONS

Kingsberg SA, Clayton AH, Portman D, Williams LA, Krop J, Jordan R, Lucas J, Simon JA. Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder "Two Randomized Phase 3 Trials". Obstet Gynecol. 2019;134:899-908

Simon JA, Kingsberg SA, Portman D, Williams LA, Krop J, Jordan R, Lucas J, Clayton AH. Long-Term Safety and Efficacy of Bremelanotide for Hypoactive Sexual Desire Disorder. Obstet Gynecol 2019;134:909-917

Kingsberg SA, Schaffir J, Faught BM, Pinkerton JV, Parish SJ, Iglesia CB, Gudeman J, Krop J, Simon JA. Female Sexual Health: Barriers to Optimal outcomes and a Roadmap for Improved Patient-Clinician Communications. J Womens Health (Larchmt). 2019

Wolf M, Chertow GM, Macdougall IC, Kaper R, Krop J, Strauss W. Randomized trial of intravenous iron-induced hypophosphatemia. JCI Insight. 2018 Dec 6;3(23)

Strauss WE, Franklin Adkinson N, Macdougall IC, Auerbach M, Kaper RF, Chertow GM, Krop JS. "A comment on the comparative safety of intravenous ferumoxytol versus ferric carboxymaltose in iron deficiency anemia. Am J Hematol. 2018 Sep;93(9):E232-E233

Adkinson, NF, Strauss WE, Macdougall IC, Bernard KE, Auerbach M, Kaper RF, Chertow GM, Krop JS. Comparative safety of intravenous ferumoxytol vs ferric carboxymaltose in iron deficiency anemia: A randomized trial. Am J Hematol. 2018 May;93(5):683-690

Adkinson, NF,Strauss WE, Bernard K, Kaper RF, Macdougall IC, Krop JS. Comparative safety of intravenous Ferumoxytol versus Ferric Carboxymaltose for the Treatment of Iron Deficiency Anemia: rationale and study design of a randomized double-blind study with a focus on acute hypersensitivity reactions. J Blood Med. 2017 Sep 26;8:155-163

J Krop, w. Kramer. Comparative Bioavailability of Hydroxyprogresterone Caproate administered via Intramuscular injection or subcutaneous autoinjector in healthy postmenopausal women: A Randomized, parallel group, open label study. Clin Ther. 2017 Dec;39(12):2345-2354

Vaccaro AR, Lawrence JP, Patel , Katz LD, Anderson DD, Fishgrund JS, Krop J, Fehlings MG, Wong, D. The Safety and Efficacy of OP-1 (rhBMP-7) as a Replacement for Iliac Crest Autograft in Posterolateral Lumbar Arthrodesis: a Long-Term (>4 years) Pivotal Study. *Spine* 33 (26) 2850-62, Dec 15, 2008.

Bertoni AG. Anderson GF. Krop JS. Brancati FL. Diabetes – Related Morbidity and Mortality in a National Sample of US Elders. [Article] *Diabetes Care.* 25(3): 471-475, 2002 Mar.

Krop JS, Weller W, Shaffer T, Saudek C, Anderson G. "Predicting Expenditures for Medicare beneficiaries with Diabetes: A Prospective Cohort Study from 1994-1996, *"Diabetes Care* 22: 1660-6, Oct. 1999.

Krop, JS., Coresh, J, Brancati, F. "Black/White Differences in the Incidence of Early Renal Function Decline Among a Community Sample of Diabetes Adults: The Atherosclerosis in Communities (ARIC) Study, " *Archives of Internal Medicine* 159: 1777-83, August 1999.

Krop JS, Weller W, Shaffer T, Saudek C, Anderson G. "Patterns of Expenditures and Use of Services Among Older Adults with Diabetes: Implications for the Transition to Capitated Managed Care", *Diabetes Care* 21: 747-752, May 1998.

Swartzman J. (Krop) and Molloy M., "The Context for Reform" in *Physician Payment Review Commission, Annual Report to Congress*, Washington, DC, 1989.

Editor for *The Johns Hopkins Complete Home Encyclopedia of Drugs*, Medletter Associates, New York, 1998.

ABSTRACTS/ PRESENTATIONS/MANUSCRIPTS

S. Kingsberg, a. Al-Khateeb, S. Karkare, N. Hadker, M. Lim-Watson, J. Krop, L. Williams. Systematic Review of HSDD and ED. *Current Medical Research & Opinion 2019*

J. Simon, S Kingsberg, D. Portman, L, Williams, J. Krop, R. Jordan, J. Lucas, A. Clayton. Long term Safety and Efficacy of Bremelanotide for Hypoactive Sexual Desire Disorder. *Obstetrics & Gynecology (Nov 2019)*

S. Kingberg, A. Clayton, D. Portman, L. Williams, J. Krop, R. Jordan, J. Lucas, J. Simon. Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder: Two Randomized Phase 3 Trials. *Obstetrics & Gynecology (Nov 2019)*

J. Simon, A. Clyaton, S. Kingsberg, D. Portman, R. Jordan, Lucas, L. Williams, J. Krop. Effect Size of Bremelanotide Treatment in the Phase 3 RECONNECT studies. *NPWH, SMSNA 2019*

S. Kingsberg, A. Clayton, D. Portman, R. Jordan, Revicki, L. Williams, J Krop. Bremelanotide Treatment Provided Clinically meaning Benefits in Premenopausal Women with Hypoactive Sexual Desire Disorder. *NPWH, SMSNA, 2019*

A. Clayton, S. Kingsberg, J. Simon, Lucas, R, Jordan Spana, l. Williams, J. Krop . Safety and Efficacy of bremelanotide in the RECONNECT Studies. *AASECT 2019*

A. Clayton, J. Simon, S ingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder: Contraceptive Subgroups Efficacy Analysis. *ASCP, AAFP 2019*

S. Kingsberg, A. Clayton, J. Simon, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Baseline Arousal Subgroups. *SSTAR, AWH 2019*

J. Simon, A. Clayton, S. Kingsberg, R, Jordan, L. Williams, J. Krop. Efficacy of Bremelanotide Across Hypoactive Sexual Desire Disorder Duration Subgroups *ACOG 2019*

A. Clayton, S. Kingsberg, J. Simon, R. Jordan, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder: Contraceptive Subgroups Efficacy Analysis *ACOG, AWAH, SMSN, A2019*

A. Clayton, J. Simon, S. Kingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Baseline Free Testosterone Level Quartile Subgroups. *ISSWSH, ASCP 2019*

A. Clayton, J. Simon, S. Kingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Co-Primary Endpoints According to Baseline FSFI Total Scores. *SMSNA 2018*

K. Spadt, Faught, R. Jordon, Lucas, L, Williams, J. Krop. Women's Experiences With Bremelanotide Administered Via Autoinjector, As Desired, for the treatment of Hypoactive Sexual Desire Disorder. *NPWH 2018*

William E. Strauss,Naomi V. Dahl. John Jiang, Kristine Bernard, Robert F. Kaper, Julie Krop. IV iron treatment of iron deficiency anaemia with Ferumoxytol in patients with inflammatory bowel disease unable to take oral iron: a randomized controlled trial versus ferric carboxymaltose.

Auerbach M, Strauss WE, Macdougall IC, Bernard K, Kaper RF, Chertow GM, Li Z, Trochanov A, Dahl NV, and Krop J. Randomized, Double-Blind Trial of Ferumoxtol compared to Ferric Carboxmaltose for treatment of iron deficiency anemia: safety and efficacy.

Presentation on “The Utility of Administrative Databases for Outcomes Research in Diabetes Mellitus”. International Conference on Outcomes Research Applied to Diabetes, January 1998 Berlin, Germany.

Krop JS, Powe NR, Weller W, Shaffer T, Saudek CD, Anderson GF. “Factors Explaining Expenditures and Utilization of Health Care Services Among Medicare Beneficiaries with Diabetes – Implications for Capitation. Presented at CDC Diabetes Translation Meeting in Ft. Lauderdale, April 1998.

Krop JS, Anderson GF, Shaffer T, Brancati. “Preventive Health Services and the Risk of Lower Extremity Amputations in Diabetic Elders: A Population-based Study”. Poster presentation at the June 1998 American Diabetes Association meeting.

Krop, JS., Coresh, J, Brancati, F. “Black/White Differences in the Incidence of Early Renal Function Decline Among a Community Sample of Diabetic Adults: The Atherosclerosis in Communities (ARIC) Study.” Oral presentation at the Robert Wood Johnson Clinical Scholars National Meeting, November, 1997. Oral presentation at the June 1998 American Diabetes Association meeting.

A Randomized Controlled Trial of a Humanized □4□7 Antibody in Ulcerative Colitis (UC) Brian Feagan, Gordon Greenberg, Gary Wild, John McDonald, Richard Fedorak, Pierre Pare, Kei Kishimoto, Jose-Carlos Guitterez-Ramos, Julie Krop, Millennium Pharmaceuticals, Inc., Robarts Clinical Trials. Oral presentation at the American Gastroenterolgy Association meeting in Orlando, Florida, May 2003.

Efficacy and Safety of a Humanized □4□7 Antibody in Active Crohn’s Disease (CD) Brian G. Feagan, Gordon Greenberg, Gary Wild, John McDonald, Richard Fedorak, Pierre Pare, Kei Kishimoto, Jose-Carlos Guitterez-Ramos, Julie Krop, Millennium Pharmaceuticals, Inc., Robarts Clinical Trials. Oral presentaion at the American Gastroenterolgy Association meeting in Orlando, Florida, May 2003.