Julia Joy Jennings

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Objective

Experienced Clinical Scientist with oncology experience seeking an opportunity for career development and advancement. Highly motivated to build on existing skills, and develop and implement processes at a small to midsize biotech.

Experience

Senior Director, Clinical Science, May 2025 - Present
Director, Clinical Science (Early Development), October 2023 - May 2025
Deciphera Pharmaceuticals, Waltham, MA

- Works closely with Medical Directors, Pharmacology, Translational Research, Discovery, external experts, and investigators to accumulate scientific and medical knowledge necessary to support clinical development plans
- Assists Medical Directors in development of concept sheets for clinical studies; contributes to authoring of clinical study protocols, amendments and related documents, as well as clinical sections of regulatory documents (IB, IND sections)
- Contributes to clinical sections of study-related regulatory submissions and responses to regulatory queries
- Monitors real time study data to ensure study integrity; interacts with investigators and internal and external experts to resolve any study issues
- Responsible for high level data cleaning activities requiring clinical judgment
- Involved in analysis of complex data for regulatory submissions, publications and design of studies and programs
- Clinical/scientific subject matter expert on products and studies in the therapeutic area
- Contributes to preparation of abstracts, manuscripts, and presentations for external meetings
- Attends scientific meetings to remain abreast of new developments within relevant areas and to interact with investigators and advisors
- Presents data, protocol designs and other information at advisory boards, investigator meetings, steering committees, site initiations and other internal and external settings

Director, Clinical Development (Clinical Scientist), December 2022 - October 2023 **Associate Director, Clinical Scientist**, November 2021 - December 2022 SQZ Biotechnologies, Watertown, MA

- Drove the accumulation of essential scientific and medical knowledge by closely working with Medical Directors, Clinical Operations, and Research teams, supporting clinical development plans and study protocols.
- Provided oversight for the medical aspects of key regulatory and communication documents, and conducted reviews of clinical trial data to ensure accuracy and efficacy.
- Guided the development of concept sheets and protocols for clinical studies, incorporating insights from internal and external experts, and directly contributing to the medical writing process.
- Led clinical contributions to regulatory responses and submissions, ensuring study and data integrity through proactive monitoring and resolution of study-related issues.
- Engaged in critical data cleaning and complex data analysis for regulatory submissions and publications. Actively participated in presenting study data and designs at various scientific and clinical forums.

Senior Manager, Clinical Research, January 2021 – November 2021 Manager, Clinical Research, January 2020 – December 2020 Clinical Research Associate II, January 2019 – December 2019 Deciphera Pharmaceuticals, Waltham, MA

- Monitored real time study data to ensure the integrity of the study; provides sites with examples of data entry errors and possible solutions to ensure understanding and meet data cut timelines
- Responsible for high level data cleaning activities requiring clinical judgment.
- Worked with investigative sites to answer protocol related questions, resolve study conduct and design issues; relieves study MD of some medical monitoring duties.
- Assisted Medical Directors in development of clinical study concepts and partners with Medical Writing to author clinical study protocols, amendments and related documents; assists in writing and concept development of ripretinib and binimetinib combination protocol.
- Presented data, protocol designs and other information at site initiation visits, protocol review committee meetings, and other internal and external settings.
- Lead the development of the master risk language for the annual IB update in partnership with Biostatistics, Medical, and Pharmacovigilance.
- Drafted clinical responses to regulatory queries.
- Interpreted analysis of complex data for regulatory submissions, publications and design of studies and programs.
- Contributed to preparation of abstracts, manuscripts, and presentations for external meetings.
- Attended scientific meetings to remain abreast of new developments within relevant areas and to interact with investigators, and advisors.
- Acted as clinical/scientific expert on the products and studies in the therapeutic area.

Clinical Trial Associate, Deciphera Pharmaceuticals, Waltham, MA February 2018 – December 2018

- Drafted, reviewed, and revised clinical documents (eg, protocols, master and site specific Informed Consents, study plans).
- Participated in study start up activities including preparation and maintenance of study reference manuals, site tools, templates, source documents and guidelines.
- Supported the study specific trial master file by filing and maintaining electronic trial master file (eTMF) for sponsor documents.
- Tracked the collection, shipment, and analysis of all study samples and coordinate distribution of clinical trial supplies, equipment, and laboratory kits.
- Verified and tracked invoices and payments for vendors and sites.
- Liaised with clinical drug supply to ensure adequate study drug inventory, facilitate site storage solutions and issue resolution.
- Collaborated with CROs, vendors and clinical sites in performing the day-to-day activities of a clinical trial, including generating management status reports, sample and drug supply tracking.

Clinical Research Coordinator I and II, May 2016 – February 2018 Clinical Administrative Support Specialist, May 2015 – May 2016 New Patient Coordinator, March 2015 – May 2015

Dana-Farber Cancer Institute, Boston, MA

- Oversaw clinical trials start-up process from receipt of protocols through the Scientific Review Committee and IRB submissions and site activation activities. Prepared regulatory reports and IRB submissions. Maintained and organized study regulatory binders.
- Reported and managed data, collected source documents, reviewed medical records to identify and report adverse events, worked with clinicians to resolve queries, and filed and archived study records.
- Obtained detailed clinical information face-to-face, by telephone, and electronically.

Lab Tech I and II, Homeyer Consulting Services, Inc. Tewksbury, MA August 2013 – February 2015

- Developed new methods and reworked existing methods to obtain improved results for chromatography and ICP equipment.
- Performed advanced troubleshooting on all laboratory equipment; updated instrument procedures and brought them up to ISO standards.
- Independently generated data and write reports for special projects.

Education	University of Massachusetts Lowell Bachelor of Science, Biology	Lowell, MA Graduate, 05/13
Relevant Coursework	Johns Hopkins University via Coursera Certificate, Design and Interpretation of Clinical Trials	Online via Coursera Completed, 06/20
	Harvard Extension School Graduate Certificate, Bioinformatics	Cambridge, MA Completed, 05/20

Publications / Conference Contributions

- Amaravad RKi, Hong DS, Weekes CD, Tolcher AW, Kummar S, Uboha NV, Vandross A, Psoinos CM, Gozo M, Davis E, Viswanathan L, <u>Jennings J</u>, Reu FJ, Mehnert J, P3.12D.08 DCC-3116 In Combination with Sotorasib in Advanced or Metastatic KRASG12C-Mutant Cancers: First-in-human Phase 1/2 Study Journal of Thoracic Oncology, Volume 19, Issue 10, Supplement, 2024, Pages S349-S350, ISSN 1556-0864 https://doi.org/10.1016/j.jtho.2024.09.630. (https://www.sciencedirect.com/science/article/pii/S1556086424015041)
- 2. Jimeno A, Iams WT, Park JC, Mita M, Holtick U, Gordon MS, Rodabaugh KJ, Dhani N, Taylor M, Duvall EA, <u>Jennings J</u>, Miselis N, Loughhead S, Warren MS, Bernstein H, and Baranda J. <u>SQZ-PBMC-HPV-101</u>: Increased overall survival in a subset of patients with recurrent, locally advanced, or metastatic <u>HPV16</u> tumors treated with cell-based vaccine, <u>SQZ-PBMC-HPV</u>. Journal for ImmunoTherapy of Cancer 2023
- 3. Villaflor V, Veluswamy R, Zsiros E, Shields AF, Joshi S, <u>Jennings J</u>, Miselis N, Loughhead S, Warren MS, Bernstein H, and Maziarz RT. *SQZ-AAC-HPV-101: Initial data from a phase I dose escalation/expansion study of SQZ-AAC-HPV, a red blood cell-based therapeutic cancer vaccine for <i>HPV16+ solid tumors*. Journal for ImmunoTherapy of Cancer 2023
- 4. Pelster M, Jimeno A, Wise-Draper T, Park JC, Villaflor V, Rodabaugh KJ, Iams WT, <u>Jennings J</u>, Morrison M, Miselis N, Loughhead S, Bernstein H, Warren MS, Moser JC, and Gordon MS. *COMMANDER-001:*Safety data from a phase I/II dose escalation/expansion study of SQZ-eAPC-HPV, a cell-based mRNA therapeutic cancer vaccine for HPV16+ solid tumors. Journal for ImmunoTherapy of Cancer 2023
- Jimeno A, Baranda J, Iams WT, Park JC, Mita M, Gordon MS, Taylor M, Dhani N, Leal AD, Neupane P, End C, Yeku O, Mita A, Moser JC, Butler M, Loughhead SM, <u>Jennings J</u>, Miselis NR, Ji RR, Nair N, Kornacker M, Zwirtes RF, Bernstein H, & Sharei A. *Phase 1 study to determine the safety and dosing* of autologous PBMCs modified to present HPV16 antigens (SQZ-PBMC-HPV) in HLA-A*02+ patients with HPV16+ solid tumors. Invest New Drugs. 2023;41(2):284-295. doi:10.1007/s10637-023-01342-x
- Moser, J., Pelster, M., Jimeno, A., Park, J. C., Iams, W. T., Wise-Draper, T., <u>Jennings, J</u>., Miselis, N. R., Ji, R. R., Loughhead, S. M., Zwirtes, R., Warren, M., Sharei, A., Bernstein, H., & Gordon, M., & (n.d.). 183p commander-001: Initial Safety Data from a phase I/II dose ... IO Tech. https://www.esmoiotech.org/article/S2590-0188(22)00226-X/fulltext
- 7. Jimeno, A., Miselis, N. R., Park, J. C., <u>Jennings, J.</u>, Dhani, N., Holtick, U., Iams, W. T., Rodabaugh, K., Nair, N., Kornacker, M., Loughhead, S. M., Bernstein, H., Zwirtes, R., Ji, R. R., Warren, M., & Sharei, A. (n.d.). *191p preliminary biomarker and safety results of SQZ-PBMC-HPV at RP2D ...* IO Tech. https://www.esmoiotech.org/article/S2590-0188(22)00234-9/fulltext
- 8. Pelster M, Gordon M, Moser J, Wise-Draper T, Park JC, Iams WT, Zwirtes R, <u>Jennings J</u>, Miselis N, Ji RR, Loughhead S, Bernstein H, Sharei A, & Jimeno A. 638 *COMMANDER-001: a phase 1/2, first-in-human, multicenter, open label study of SQZ-eAPC-HPV as monotherapy and with pembrolizumab in patients with HPV16+ recurrent, locally advanced, or metastatic solid tumors (trial in progress) Journal for ImmunoTherapy of Cancer 2022;10:doi: 10.1136/jitc-2022-SITC2022.0638*
- 9. Park JC, Bernstein H, Loughhead S, Zwirtes R, <u>Jennings J</u>, Nicolini V, Klein C, Deak LC, Umana P, Trumpfheller, & Sharei A. *Cell Squeeze: driving more effective CD8 T-cell activation through cytosolic antigen delivery.* Immunooncol Technol. 2022;16:100091. Published 2022 Jul 8. doi:10.1016/j.iotech.2022.100091
- 10. Villaflor, V., Veluswamy, R., Garralda, E., Maziarz, R., Zsiros, E., Shields, A., Ponz-Sarvise M., Lolkema M., Brahmi M., Jennings J., Miselis N., Moore L., Blagovic K., Ji R. R., Loughhead S., Zwirtes R., & Patel, S. (2022). Abstract CT241: ENVOY-001: A phase 1, multicenter, open-label study of SQZ-AAC-HPV as monotherapy and in combination with immune checkpoint inhibitors in HLA-A* 02+ patients with HPV16+ recurrent, locally advanced, or metastatic solid tumors. Cancer Research, 82(12_Supplement), CT241-CT241.

- George, S., Chi P., Heinrich, M. C., von Mehren, M., Jone, R. L., Ganjoo, K., Trent, J., Gelderblom, H., Razak, A. R. A., Gordon, M., Somaiah N., Jennings, J., Shi, K., Ruiz-Soto, R., Janku, F. (2020, November 18-21). Ripretinib Intra-Patient Dose Escalation Following Disease Progression Provides Clinically Meaningful Progression-Free Survival in Gastrointestinal Stromal Tumor in Phase 1 Study [Conference abstract and oral presentation]. Connective Tissue Oncology Society Conference 2020, Virtual.
- 12. Janku, F., Chi, P., Heinrich, M. C., von Mehren, M., Jones, R. L., Ganjoo, K., Trent, J., Gelderblom, H., Razak, A. R. A., Gordon M., Somaiah, N., Jennings J., Shi, K., Ruiz-Soto, R., George, S. (2020, September 19-21). Ripretinib Intra-patient Dose Escalation (IPDE) Following Disease Progression Provides Clinically Meaningful Progression-Free Survival (PFS) in Gastrointestinal Stromal Tumor (GIST) in Phase 1 Study [Conference abstract and mini-oral presentation]. European Society for Medical Oncology 2020, Virtual.
- Somaiah, N., Razak, A. R. A., Gordon, M., Janku, F., Friedlander, S., Flynn, D., Kaufman, M., Pitman, J., Ruiz-Soto, R., Smith, B., Westwood, D., <u>Jennings, J.</u>, Jacobson, J., Rosen, O., George, S. (2017, November 8-11). DCC-2618, A NOVEL PAN-KIT AND PDGFRA KINASE SWITCH CONTROL INHIBITOR DEMONSTRATES ENCOURAGING ACTIVITY IN PATIENTS (PTS) WITH GASTROINTESTINAL STROMAL TUMORS (GIST) [Conference abstract]. Connective Tissue Oncology Society Conference 2017, Maui, Hawaii.
- 14. Ben Ami, E., Kamran, S. C., George, S., Morgan, J. A., Wagner, A. J., Merriam, P., Thornton, K. A., <u>Jennings, J.</u>, Field, J., Solomon, R., Raut, C. P., Van Allen, E. M., Demetri, G. D. (2017, June 2-6). Whole exome analysis of patients (pts) with metastatic GIST (mGIST) demonstrating exceptional survival with imatinib (IM) therapy compared to those with short term benefit. [Conference abstract and poster]. American Society of Clinical Oncology Conference 2017, Chicago, Illinois.