

Alyssa N. Birt

Nonclinical Consultant

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Summary:

Nonclinical development consultant and strategic R&D leader with 15+ years of experience advancing cell therapy and biologics programs from discovery through IND. Experienced in managing preclinical development plans, coordinating IND-enabling activities, and guiding regulatory documentation across complex programs. Strong background partnering with academic collaborators, CROs, and cross-functional teams to align scientific objectives, study execution, timelines, data packages, and corporate priorities. Skilled at translating early-stage research into practical development strategies, overseeing external study work, integrating results across contributors, and preparing clear, submission-focused narratives for reports and IND Modules.

Work Experience:

BioBirty Consulting LLC

May 2025 - present

Principal Consultant

- Nonclinical and translational development strategy tailored to program stage, regulatory path, and company goals.
- IND-enabling study planning and oversight, including toxicology, biodistribution, DMPK, pharmacology, efficacy, and safety studies.
- Management of academic collaborations, with a focus on translating investigator- and founder-generated research into practical development plans.
- CRO and vendor oversight, including study scoping, protocol review, timeline management, data review, interpretation of results, and final report review.
- IND writing and regulatory documentation, including Module 4 reports, Module 2 summaries, nonclinical overviews, study narratives, and integrated data packages.
- Synthesis of academic data, CRO reports, and internal research findings into clear scientific, regulatory, investor, and corporate development materials.
- Preparation of investor, board, diligence, and partnering materials to support capital raises, strategic planning, and corporate development.
- R&D budget development, study cost forecasting, vendor planning, and operational support from early research through IND-enabling execution.

AffyImmune Therapeutics, Natick, MA

December 2020 – January 2025

Associate Director, Preclinical Development

March 2024 – January 2025

- Led the execution of functional goals as Head of R&D, overseeing platform development and cross-functional non-clinical support.
- Contributed to non-clinical sections for indication expansion filings, including IND amendments and Briefing Books for Agency interactions, with a focus on immunohistochemistry, potency assays, binding affinity assays, and CAR T characterization.
- Served as a non-clinical member of the Program Team, identifying program risks and collaborating with CMC, clinical, and regulatory teams to meet deliverables.

- Reported directly to the CEO and represented the Preclinical Development function on the Executive Team, advocating for employee interests in corporate decision-making, HR policies, and cultural initiatives.
- Expanded AffyImmune's patent estate by identifying opportunities and partnering with counsel to file or supplement five provisional patents as Associate Director. Developed novel scFv binders to known tumor antigens, provided proof of concept data for use as CAR T, antibody and antibody drug conjugates.
- Developed and presented materials for scientific advisory board meetings, leading discussions and contributing to strategic direction.
- Represented the company at national conferences, presenting preclinical data to industry professionals at AACR and SITC.

Senior Scientist, Research and Development

July 2022 – March 2024

- Led platform development of novel affinity-tuned CAR T for preclinical development including design, cloning, virus production, and manufacturing of novel constructs.
- Developed analytical based assays for testing efficacy and toxicity in tumor and primary cell lines.
- Spearheaded the selection of non-small cell lung cancer as the second indication for AIC100, organizing and managing a team of on-site and CRO experts to deliver the preclinical data package.
- Provided in vivo modeling and design strategies for R&D, managing CRO relationships to ensure optimal execution.
- Supported CMC and clinical development by leveraging experience to develop analytical assays, process improvements, and deepen understanding of the clinical product's mode of action.
- Managed a team of scientists, fostering their growth and success in a fast-paced, collaborative environment.

Scientist II, Research and Development

December 2020 – July 2022

- Led R&D-scale LVV and CAR T manufacturing to advance pipeline projects and in vivo studies. Established and optimized small scale lentiviral production system and CAR T manufacturing to allow for higher throughput screening.
- First hire with a molecular biology background, established design and cloning capabilities in house which shortened the time between idea and testing of new constructs.
- Researched, compared and managed CROs to support clinical manufacturing of GMP-grade lentivirus.

Aleta Biotherapeutics, Natick, MA

September 2017 – December 2020

Scientist II, Molecular and Cellular Biology

March 2020 – December 2020

- Researched, designed, and evaluated new constructs for multi-targeted approaches, supporting both biologics and CAR T cell therapy pipeline projects.
- Served as subject matter expert in construct design for biologic and CAR T programs, presenting to the executive team to inform go/no-go decisions and pipeline prioritization.
- Innovated new technologies and protocols by attending conferences, conducting literature reviews, testing manufacturing processes, and building relationships with new vendors to expand Aleta's "toolbox."
- Designed and performed small-scale primary T cell expansions, testing new constructs for transduction efficiency and efficacy in vitro before scaling up for in vivo testing.

- Designed and constructed lentiviral vectors for CAR T cell applications, assessing design feasibility and efficacy.
- Optimized and executed small-scale lentivirus production for in vitro characterization in SUPT1 and primary human T cell experiments, enhancing throughput capabilities.
- Performed flow cytometry and luminescence assays to characterize fusion proteins for multiantigen targeting platforms, guiding decisions on which assets to advance.

Quiet Therapeutics, Lexington, MA

September 2016 – July 2017

Senior Associate Scientist, Biology

- Designed and optimized plasmid constructs for the company's first immuno-oncology vectors.
- Set up molecular biology assays, including restriction digest cloning, Gibson cloning, Western blot, ELISAs, and endotoxin assays.
- Tested plasmid constructs in vitro for expression using ELISA and flow cytometry.
- Assisted in the build out, move and expansion of laboratory space from leased co-lab space to brand new facilities in Lexington.

Bluebird Bio, Cambridge, MA

April 2015 – September 2016

Associate Scientist, Immunotherapy

- Designed and constructed lentiviral vectors to support gene therapy and immunotherapy platforms.
- Produced small-scale lentiviral vectors and transduced human cells for experimentation.
- Conducted microculture scale T-cell experiments to test new vector designs.
- Developed small-scale mRNA productions for rapid in vitro testing of new targets for the CAR T program.
- Expanded the molecular "toolbox" for the CAR T program by investigating alternative promoter and enhancer systems.

Mascoma Corporation, Lebanon, NH

August 2013 - January 2015

Research Associate, Genetic Engineering

- Collaborated with a team to develop genetically engineered yeast strains for biomass-to-fuel conversion.
- Engineered yeast strains using techniques such as Gibson cloning, electrophoresis, genomic and plasmid preparation, directed integration, and PCR.
- Assembled, operated, and optimized small-scale fermentations in 96 deep-well plates and 10 mL mini vials to test engineered strains.

Pennsylvania State University

August 2011 - August 2013

Graduated Research Assistant in Dr. Troy Ott's Laboratory

- Developed and characterized an immortalized bovine uterine epithelial cell line as a model to study maternal recognition of pregnancy (~day 20) and the role of interferon tau in triggering gene upregulation for pregnancy detection in cows.

**University of New Hampshire
2011**

January 2009 – May

Research Assistant in Dr. Subhash Minocha's Laboratory

- Studied regulation and expression of the polyamine pathway.

- Genetically engineered poplar cells utilizing biolistic techniques (gene shooting).

Research Assistant in Dr. David Townson's Laboratory

- Summer Fellowship was awarded from the Hamel Center for Undergraduate Research.
- Aimed to detect the mRNA expression of FAS during different stages of the estrus cycle in cows utilizing RNA extraction, cDNA synthesis, and quantitative polymerase chain reaction.

Publications:

- Yang Y, Yang H, Alcaina Y, Puc J, **Birt A**, Vedvyas Y, Gallagher M, Alla S, Riascos MC, McCloskey JE, Du K, Gonzalez-Valdivieso J, Min IM, de Stanchina E, Britz M, von Hofe E, Jin MM. Inducible expression of interleukin-12 augments the efficacy of affinity-tuned chimeric antigen receptors in murine solid tumor models. *Nat Commun*. 2023 Apr 12;14(1):2068. doi: 10.1038/s41467-023-37646-y. PMID: 37045815; PMCID: PMC10097865.
- Ambrose C, Su L, Wu L, Dufort FJ, Sanford T, **Birt A**, Hackel BJ, Hombach A, Abken H, Lobb RR, Rennert PD. Anti-CD19 CAR T cells potently redirected to kill solid tumor cells. *PLoS One*. 2021 Mar 18;16(3):e0247701. doi: 10.1371/journal.pone.0247701. PMID: 33735268; PMCID: PMC7971483.
- Rennert PD, Dufort FJ, Su L, Sanford T, **Birt A**, Wu L, Lobb RR, Ambrose C. Anti-CD19 CAR T Cells That Secrete a Bipartite Anti-CLEC12A Bridging Protein Have Potent Activity Against Highly Aggressive Acute Myeloid Leukemia *In Vitro* and *In Vivo*. *Mol Cancer Ther*. 2021 Oct;20(10):2071- 2081. doi: 10.1158/1535-7163.MCT-20-1030. Epub 2021 Jul 12. PMID: 34253594.
- Klesmith JR, Su L, Wu L, Schrack IA, Dufort FJ, **Birt A**, Ambrose C, Hackel BJ, Lobb RR, Rennert PD. Retargeting CD19 Chimeric Antigen Receptor T Cells via Engineered CD19Fusion Proteins. *Mol Pharm*. 2019 Aug 5;16(8):3544-3558. doi: 10.1021/acs.molpharmaceut.9b00418. Epub 2019 Jul 15. PMID: 31242389.
- Kin, K., Maziarz, J., Chavan, A. R., Kamat, M., Vasudevan, S., **Birt, A.**, Emera, D., Lynch, V., Ott, T., Pavlicev, M., Wagner, G. P. (2016). The transcriptomic evolution of mammalian pregnancy: gene expression innovations in endometrial stromal fibroblasts. *Genome Biology and Evolution*. <http://doi.org/10.1093/gbe/evw168>
- Ribeiro ES, Bruno RG, Farias AM, Hernández-Rivera JA, Gomes GC, Surjus R, Becker LF, **Birt A**, Ott TL, Branen JR, Sasser RG, Keisler DH, Thatcher WW, Bilby TR, Santos JE. Low doses of bovine somatotropin enhance conceptus development and fertility in lactating dairy cows. *Biol Reprod*. 2014 Jan 16;90(1):10. doi: 10.1095/biolreprod.113.114694. Print 2014 Jan. PubMed PMID: 24285716.
- Duncan, Alice, Jennifer Forcina, **Alyssa Birt**, and David Townson. 2012. "Estrous Cycledependent Changes of Fas Expression in the Bovine Corpus Luteum: Influence of Keratin 8/18 Intermediate Filaments and Cytokines." *Reproductive Biology and Endocrinology: RB&E* 10: 90. doi:10.1186/1477- 7827-10-90.

Relevant Posters:

- **Birt A**, Josiah S, Alla S, et al. AIC100 CAR T cells show clear potential for the treatment of ICAM-1 positive non-small cell lung cancer. *Journal for Immunotherapy of Cancer* 2024;12:doi: 10.1136/jitc-2024-SITC2024.0242

- **Alyssa Birt**, Serene Josiah, Kelsey L. Joyce, Srinija Alla, Michael P. Gallagher, Janusz Puc, Hanh Nguyen, Emily Walsh Martin, Sonal Gupta. AIC100 CAR T cells targeting ICAM-1 are efficacious against solid tumors in xenograft mouse models of non-small cell lung cancer (NSCLC) and cervical cancer (CC) [abstract]. In: Proceedings of the American Association for Cancer Research Annual Meeting 2024; Part 1 (Regular Abstracts); 2024 Apr 5-10; San Diego, CA. Philadelphia (PA): AACR; Cancer Res 2024;84(6_Suppl):Abstract nr 4007.
- Yanping Yang, Huan Yang, Yago Alcaina, Jaclyn E. McCloskey, Janusz Puc, **Alyssa Birt**, Yogindra Vedvyas, Juan Gonzalez-Valdivieso, Irene M. Min, Eric von Hofe, Moonsoo M. Jin. Revitalization of affinity-tuned CAR T cells via antigen-dependent release of interleukin-12 [abstract]. In: Proceedings of the American Association for Cancer Research Annual Meeting 2022; 2022 Apr 8-13. Philadelphia (PA): AACR; Cancer Res 2022;82(12_Suppl):Abstract nr 5568.
- Rennert P, **Birt A**, Su L, et al.133 Development of novel cellular therapeutics for metastatic and primary CNS malignancies [abstract]. Journal for ImmunoTherapy of Cancer 2020;8:doi: 10.1136/jitc-2020-SITC2020.0133
- Paul Rennert, Christine Ambrose, Lihe Su, Fay Dufort, **Alyssa Birt**, Tom Sanford, Lan Wu, Roy Lobb. CAR-CD19 T cells secreting multi-antigen bridging proteins eliminate solid tumors [abstract]. In: Proceedings of the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics; 2019 Oct 26-30; Boston, MA. Philadelphia (PA): AACR; Mol Cancer Ther 2019;18(12 Suppl): Abstract nr B020. doi:10.1158/1535-7163.TARG-19-B020
- Paul Rennert, Fay Dufort, Lihe Su, Lan Wu, **Alyssa Birt**, Christine Ambrose, Roy Lobb. Hijacking CAR19 T-cells for use in targeting diverse hematopoietic and solid tumors [abstract]. In: Proceedings of the Fourth CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival; Sept 30-Oct 3, 2018; New York, NY. Philadelphia (PA): AACR; Cancer Immunol Res 2019;7(2 Suppl):Abstract nr A040.

Education:

Pennsylvania State University, State College, PA

August 2013

M.Sc. - Thesis: *Development and Characterization of a Bovine Uterine Epithelial Cell Line and the Effects of Pregnancy on Gene Expression in Peripheral Blood Leukocytes*

University of New Hampshire, Durham, NH

May 2011

B.Sc. - Thesis: *Expression of FAS in the Bovine Corpus Luteum*