ARTURO ORLACCHIO, PhD, RAC-Drugs, CSSBB

Translational R&D & Drug Development | Biomarker Strategy | Preclinical Pharmacology

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PROFESSIONAL SUMMARY

Translational scientist with 12+ years of experience across oncology, preclinical drug discovery, biomarker development, and molecular diagnostics. Experience spans target validation, mechanism-of-action studies, in vivo pharmacology, assay development, and analytical validation across pancreatic, lung, and thyroid cancers. Currently leads early drug-development work at Tessering Biosciences and serves as Scientific Advisor to Episteme Prognostics in precision-oncology diagnostics. Holds RAC-Drugs and ASQ Certified Six Sigma Black Belt credentials and applies Quality by Design, reproducible data analysis, and statistical process control to strengthen experimental rigor and development decisions. Author or co-author of 15 peer-reviewed publications and 15 conference presentations and posters, with experience coordinating multidisciplinary research teams, clinical collaborators, vendors, and CROs.

CORE COMPETENCIES

Preclinical In Vivo Pharmacology (PDX, CDX, GEMM, Syngeneic, Humanized) | Translational Strategy & Drug Development | Tumor Immunology & Immuno-Oncology | Biomarker Discovery & Validation | PK/PD & Efficacy Study Design | IND-Enabling Study Design | CRO & Vendor Management | Assay Development, Validation & Tech Transfer | Companion Diagnostics (CDx) | CLIA/CLEP LDT Validation | Six Sigma & QbD | CRISPR/Cas9 & Functional Genomics | NGS | Cross-Functional Leadership

PROFESSIONAL EXPERIENCE

Tessering Biosciences, Valhalla, NY **06/2026 – Present**

Principal Scientist

- Lead translational and preclinical strategy for an early-stage small-molecule drug-development program, defining assay strategy, lead-optimization studies, translational pharmacology, and the nonclinical roadmap toward candidate selection and IND-enabling development.
- Design and execute the in vitro pharmacology, ADME, and PK/PD studies that support lead optimization, characterizing compound potency, selectivity, and developability.
- Build the company's core R&D infrastructure: laboratory operations, external study coordination, vendor and CRO management, documentation systems, and reproducible experimental workflows.

Episteme Prognostics, Inc., Brooklyn, NY **01/2024 – Present**

Scientific Advisor (consultant, 06/2026 – Present) · Principal Scientist (02/2025 – 06/2026) · Senior Scientist (01/2024 – 02/2025)

- Led a cross-functional team identifying and validating novel prognostic biomarkers for pancreatic ductal adenocarcinoma (PDAC), advancing 2 assays from discovery through analytical validation and clinical-trial readiness.
- Partnered with the Laboratory Director to validate two laboratory-developed tests (LDTs) — an HNF1B IHC assay and a chromatin-accessibility (ATAC) assay — and supported their New York State CLEP submissions, both submitted on schedule; validation demonstrated pooled precision of 3.28% CV, inter-operator ICC of 0.989, and performance evaluation in 29 clinically characterized PDAC specimens.
- Coordinated a four-site prospective validation study (two New York City centers and two out-of-state sites) extending the chromatin-accessibility assay from resected tissue to fine-needle biopsy specimens; served as point of contact for site investigators, assembled longitudinal clinical follow-up data, and analyzed overall and progression-free survival.
- Authored SOPs, validation plans, and CLIA/CLEP-aligned QC frameworks that established validated input requirements, precision criteria, traceability controls, and objective assay acceptance thresholds.
- Designed and executed in vitro and in vivo studies characterizing mechanism of action, efficacy, and potency of small molecules and biologics in pancreatic cancer; supervised and mentored a team of 3 scientists.

NYU Grossman School of Medicine, New York, NY **06/2021 – 01/2024**

Senior Research Scientist (10/2023 – 01/2024) | Research Scientist (06/2021 – 10/2023)

- Led a translational PDAC drug-discovery program that identified an epigenetically regulated macrophage-polarization mechanism limiting immunotherapy response; showed that combining hypomethylating therapy with low-dose HDAC inhibition improved efficacy in preclinical models.
- Designed and optimized in vitro immune co-culture systems modeling the tumor microenvironment and standardized immune-profiling assays, enabling reproducible biomarker discovery.
- Executed 100+ mouse survival surgeries and 100+ in vivo/in vitro drug treatments across orthotopic PDAC and other oncology models, supporting multiple discovery programs; managed multiple colonies and authored IACUC/IRB protocols.
- Collaborated with clinical investigators to align experimental outputs with patient outcomes; trained and supervised junior staff, improving consistency and reproducibility.

The Ohio State University Wexner Medical Center, Columbus, OH **08/2017 – 06/2021**

Postdoctoral Researcher

- Led NSCLC drug-discovery studies identifying novel targets that improved standard-chemotherapy efficacy in preclinical models; elucidated the role of the CTLH complex in therapeutic resistance (J Exp Clin Cancer Res, 2025).
- Generated a conditional knockout mouse model and two constitutive CRISPR/Cas9 single-nucleotide knock-in models; produced 20+ cellular models and 5 mouse models supporting multiple programs.

Albert Einstein College of Medicine, Bronx, NY **09/2013 – 08/2017**

Research Fellow

- Led a target-discovery program in anaplastic thyroid cancer (ATC) dissecting the PI3K pathway; identified and functionally validated AGC kinases (including SGK1) as oncogenic drivers (Cancer Research, 2017).
- Established pharma collaborations to evaluate kinase inhibitors; optimized a primary thyrocyte culture platform, developing 30+ cellular models that supported 100+ in vitro and in vivo drug studies.

TECHNICAL SKILLS

- **In Vivo Pharmacology:** Tumor implantation (orthotopic pancreatic, subcutaneous, tail vein); survival surgery; drug dosing (IP, IV, PO); efficacy and PK/PD study design; GEMM, CDX, PDX, syngeneic, and humanized models of PDAC, NSCLC, and thyroid cancer.
- **Clinical / Diagnostic:** Tumor tissue and blood processing; cfDNA extraction; NGS library prep (liquid biopsy); ATAC-seq and target enrichment; histology, IHC, immunofluorescence.
- **Immunology & Functional Assays:** Primary human/mouse T-cell and macrophage isolation, activation, and polarization; flow cytometry; ELISA; cytokine secretion; viability/apoptosis assays.
- **Molecular Biology & Gene Editing:** CRISPR/Cas9 knockout/knock-in and gRNA library screens; siRNA/shRNA; lentiviral transduction; PCR/qPCR; Western blot; immunoprecipitation; engineered cell-line generation.
- **Computational:** Python (reproducible data-analysis workflows), GraphPad Prism, FlowJo, ImageJ, Benchling, GSEA, IPA, UCSC Genome Browser, JASP.

EDUCATION

PhD, Molecular Biology University of Sannio, Benevento, Italy

MS, Genetic Sciences and Technologies University of Sannio, Benevento, Italy

CERTIFICATIONS

- Regulatory Affairs Certification (RAC-Drugs), 2026 — Regulatory Affairs Professionals Society (RAPS)
- ASQ Certified Six Sigma Black Belt (CSSBB), 2025

SELECTED PUBLICATIONS

- Orlacchio A, Kajimura Y, Rizzotto L, et al. *"RANBP9 and RANBP10 cooperate in regulating non-small cell lung cancer proliferation."* J Exp Clin Cancer Res. 2025;44:259.
- Orlacchio A, Ranieri M, Brave M, et al. *"SGK1 is a critical component of an AKT-independent pathway essential for PI3K-mediated tumor development and maintenance."* Cancer Res. 2017;77(24):6914-6926.

Full publication list: www.orlacchioresearch.com | ORCID: 0000-0002-6044-4258