ARTURO ORLACCHIO, PhD, CSSBB

Translational Oncology Scientist | Biomarker Strategy, Analytical Validation & Preclinical Development | NYS CLEP LDTs | Reproducible Python Analysis

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PROFESSIONAL SUMMARY

Translational oncology scientist with 10+ years connecting cancer biology, biomarker assay development, preclinical models, and reproducible data analysis to support oncology R&D decisions. Led analytical validation and NYS CLEP submission packages for two precision-oncology laboratory-developed tests, including IHC- and chromatin-accessibility–based assays. Experienced across biotech, precision diagnostics, and academic settings, with strengths in in vivo oncology pharmacology, functional assays, cfDNA/genomics, IHC, SOP development, QC frameworks, and cross-functional execution. ASQ Certified Six Sigma Black Belt focused on assay robustness, reproducibility, statistical process control, and decision-grade translational data.

SELECTED TRANSLATIONAL R&D IMPACT

Biomarker & Analytical Validation

- Led analytical validation and NYS CLEP submission packages for two precision-oncology LDTs (IHC-based and chromatin-accessibility–based), generating performance documentation and assay-quality evidence relevant to precision-medicine and CDx-adjacent biomarker programs.
- For the chromatin-accessibility LDT, established analytical performance across a multi-phase validation: pooled precision ~3.3% CV with inter-operator agreement (ICC ≈ 0.99) within the <10% CV acceptance criterion; defined minimum input limits (50 ng DNA / 5,000 enriched cells); and clinical concordance in a 30-patient PDAC cohort with significant association to disease-free and overall survival.
- Authored SOPs, validation plans, and QC frameworks aligned with CLIA/CAP LDT principles, with immunocytochemistry as an orthogonal confirmation of enrichment.

Preclinical Oncology & Translational Pharmacology

- Led a PDAC immuno-oncology program at NYU: identified an epigenetically driven myeloid-polarization mechanism of anti–PD-1 resistance, then used immune co-culture with Bliss/Loewe synergy analysis to design a low-dose hypomethylating + HDAC-inhibitor combination that improved survival with anti–PD-1 in an orthotopic KPC model — mechanism → combination design → in vivo validation.
- Designed and executed in vivo/in vitro oncology studies across orthotopic PDAC and other models (100+ survival surgeries, 100+ drug treatments), with PD readouts and translational interpretation.

Reproducible Data & Quality

- Maintains reference implementations of CI-tested Python analysis workflows (dose-response/IC50, survival, PK/PD, ROC, SPC/control charts, RNA-seq/ATAC), demonstrating reproducible-analysis discipline.
- Applies Six Sigma (statistical process control, QC frameworks) to assay robustness, variability reduction, and R&D data integrity.

CORE EXPERTISE

Translational Biomarker Strategy · Analytical Assay Validation (CLIA/CLEP LDTs) · Precision Medicine & Patient-Selection Biomarkers · Immuno-Oncology & Combination Therapy · Preclinical In Vivo Pharmacology (PDX, CDX, GEMM, syngeneic, humanized) · cfDNA/NGS & ATAC-seq · IHC / immunofluorescence · CRISPR/Cas9 & functional genomics · Reproducible Python analysis · Six Sigma QbD / SPC · Cross-functional R&D execution

PROFESSIONAL EXPERIENCE

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

Principal Scientist

- Contributes to early therapeutic-development planning — assay-cascade design, preclinical study strategy, pharmacology readouts, IACUC documentation, vendor/core coordination, and nonclinical milestone planning.

- Builds R&D quality infrastructure applying Quality-by-Design and Six Sigma for reproducibility and data integrity.

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

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

- Led a cross-functional team validating novel PDAC prognostic biomarkers from discovery through analytical validation and clinical-trial readiness; drove companion-diagnostic-adjacent strategy aligned with clinical studies.
- Partnered with the Laboratory Director on the two CLEP LDT submissions; supervised and mentored scientists in experimental design, data analysis, and documentation.

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

Senior Research Scientist | Research Scientist

- Led a translational PDAC drug-discovery program (see Impact); built in vitro immune co-culture and immune-profiling assays; authored IACUC/IRB protocols.

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

Postdoctoral Researcher

- Identified novel NSCLC targets improving chemotherapy efficacy (CTLH complex in resistance); built a conditional knockout and two CRISPR/Cas9 knock-in mouse models plus 20+ cellular models.

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

Research Fellow

- Led an anaplastic thyroid cancer target-discovery program (PI3K pathway), validating AGC kinases including SGK1 as oncogenic drivers (first-author, Cancer Research 2017).

Early Career (2009 – 2013): Research Associate, Biogem Institute of Genetic Research; EMBO Short-Term Fellow, EMBL Heidelberg; Research Assistant, Stazione Zoologica Anton Dohrn, Italy.

COMPUTATIONAL PORTFOLIO

github.com/orlacchioresearch — CI-tested Python analysis workflows: IC50/dose-response and drug-combination synergy, PK/PD and tumor-growth-inhibition modeling, Kaplan-Meier/Cox survival, ROC/AUC, statistical process control (Westgard/Levey-Jennings), and RNA-seq/ATAC-seq exploratory analysis (reference implementations on synthetic/public data).

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.

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CERTIFICATIONS & TRAINING

- **ASQ Certified Six Sigma Black Belt (CSSBB), 2025** — Credential ID 165966704
- **Regulatory Affairs Certification (RAC, Drugs) — in progress**

EDUCATION

PhD, Molecular Biology University of Sannio, Benevento, Italy

MS, Medical Biotechnologies University of Sannio, Benevento, Italy