



Star Biopharma Solutions

TRANSLATIONAL SCIENCE · PRECLINICAL DEVELOPMENT · GENOMIC & BIOMARKER ANALYSIS

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15+

YEARS IN RESEARCH

22

PEER-REVIEWED PUBLICATIONS

450+

CITATIONS

7

THERAPEUTIC AREAS

WHAT WE DO

Star Biopharma Solutions LLC is a principal-led scientific and genomic consultancy serving biotechnology sponsors, contract research organizations, diagnostics and ingredient developers, and academic spin-outs. We design the programs that answer a sponsor's real question, interpret the data those programs generate, and deliver it as a written report that can be acted on, filed, or published.

We own no instruments, and that is deliberate. There is no incentive to route your work toward equipment that needs keeping busy. Advice on which CRO to use, which assay to run, and whether a dataset supports the conclusion being drawn from it is given without a commercial stake in the answer — which is exactly why sponsors ask for it. Data arrives from your laboratory, your core facility, or your vendor, on whatever system produced it.

CORE SERVICE LINES

Genomic & Multi-Omic Interpretation. Bulk and single-cell RNA-seq, whole-genome and whole-exome, 16S and ITS amplicon, and microarray data taken from FASTQ or count matrix through QC, differential expression, and pathway interpretation (PartekFlow, GSEA, ShinyGO, STRING, R, Python).

Bacterial Strain Identification, Characterization & GRAS Safety. Whole-genome taxonomic identification to species and strain level, genome assembly and annotation, and systematic screening for antimicrobial resistance determinants, virulence factors, and toxigenic potential — assembled into the safety assessment supporting a GRAS determination.

Preclinical Program Design & Execution. Model selection, endpoint definition, power and sample-size rationale, and protocol authorship. Rodent microsurgery, right-heart catheterization, xenograft and experimental carcinogenesis models, and fetal sheep inflammation models. Author of 30+ approved IACUC protocols.

Histopathology, Tissue Imaging & Image Analysis. IHC and immunofluorescence assay development on FFPE and frozen sections; brightfield, fluorescence, and confocal imaging; whole-slide scanning with QuPath quantification, scoring strategy, and blinded read design.

Predictive & Prognostic Biomarker Strategy. Moving a discovery-stage signature toward an assay a clinical or diagnostic program can use: candidate triage, analytical feasibility, specimen and cohort strategy, and alignment to FDA IVD and companion diagnostic pathways.

Patient-Derived Organoids & Ex Vivo Models. Organoids established from primary surgical and biopsy tissue under IRB approval (colon, breast, pancreatic neuroendocrine), tumoroid and 3D Matrigel systems, mouse mammary organ culture, and CRISPR-edited or lentivirally transduced stable lines.

Immunophenotyping & Cell Therapy Characterization. 12+ color flow cytometry panel design, compensation, gating strategy, and FlowJo analysis; characterization of genetically modified T-cell products; multiplex cytokine, ELISA, Luminex, and MSD interpretation.

Scientific & Regulatory Writing. IND-enabling nonclinical summaries, study protocols and reports, GRAS safety narratives, IACUC and IRB submissions, manuscripts, and SBIR/STTR proposals. Journal editor and peer reviewer across six titles.

CRO Selection & Sponsor-Side Oversight. Independent technical review of vendor deliverables — histology quality, sequencing analysis choices, flow panel design, statistical handling — so problems surface before they become expensive.

WHY SPONSORS ENGAGE US

- Rare and orphan pulmonary, cardiovascular, and neonatal indications where few consultants have hands-on model experience.
- A single point of contact spanning study design, tissue readout, and genomic interpretation — removing handoffs between three separate vendors.
- Microbiology and genomics under one roof, which is exactly the combination a strain safety or GRAS package requires.
- Every engagement ends in a report that can be independently reproduced — figures, methods, statistics, and the analysis code.

THERAPEUTIC & INDICATION EXPERIENCE

Pulmonary & Vascular	Pulmonary arterial hypertension, hypoxic pulmonary hypertension, pulmonary fibrosis, bronchopulmonary dysplasia, congenital diaphragmatic hernia
Neonatal & Perinatal	Necrotizing enterocolitis, neonatal hypoxic-ischemic brain injury, intra-amniotic inflammation, fetal systemic inflammatory response
Cardiovascular	Sickle cell cardiomyopathy and ventricular arrhythmia, myocardial infarction imaging, diastolic dysfunction genomics
Neurology	Peripheral nerve injury and Schwann cell repair, allopregnanolone neuroprotection in hypoxic-ischemic injury, genomic profiling in undiagnosed rare neurological disease
Microbial & Food Safety	Probiotic, starter culture and fermentation strains; taxonomic identification and genome characterization; resistance and virulence screening; GRAS safety assessment
Oncology	Breast (hormone-receptor positive, aromatase-inhibitor resistant), colorectal and FAP, pancreatic neuroendocrine, lung, gastric metaplasia; experimental carcinogenesis, drug repurposing

DATA IN, REPORT OUT

Data accepted	Sequencing (bulk and single-cell RNA-seq, WGS, WES, amplicon, microarray); whole-slide images, IHC/IF and confocal stacks; FCS cytometry files; ELISA, Luminex, MSD and qPCR output
What the client receives	A written report with annotated publication-grade figures, a reusable methods section, a statistical appendix, and the analysis code so the result is independently reproducible

REPRESENTATIVE PROJECT EXPERIENCE

- A CHAT-expressing T-cell vasodilator strategy for pulmonary arterial hypertension — designed and executed the full preclinical package including adenoviral transduction optimization, flow characterization of the engineered product, and right-ventricular systolic pressure endpoints. Published as first author in Translational Research (2025).
- UCHL1 deubiquitinase as a therapeutic target in PAH — target validation across transgenic models, exome sequencing SNP discovery, and in-vivo inhibitor efficacy studies. Published in Circulation (co-first author, 2024).
- IL-18 as a mediator of sickle cell cardiomyopathy and ventricular arrhythmia, established in knockout models with ex-vivo and in-vivo tachycardia endpoints (Blood, first author). NAMPT separately identified as a target in experimental necrotizing enterocolitis via NGS transcriptomics (Biomedicines, 2024).
- Desiccation resistance of Enterobacter sakazakii isolates from environmental, product, and clinical sources — conducted at the National Center for Food Safety and Technology and presented to the International Association for Food Protection.

PRINCIPAL

Akash Gupta, Ph.D., M.L.S. Cert. — Founder & Principal Scientist. Ph.D. in Biology, Illinois Institute of Technology; M.Sc. Biotechnology and B.Sc. Microbiology, University of Madras. Graduate Certificates in Clinical Research Management (Arizona State University) and Regulatory Science (University of Arizona, with Chicago-Kent College of Law and the Critical Path Institute). Prior roles: Scientist IV and Assistant Research Scientist, University of Arizona; Senior Postdoctoral Fellow, UA Cardiology; Postdoctoral Fellow, Robert H. Lurie Comprehensive Cancer Center, Northwestern University; Research Biologist, IIT Research Institute (preclinical CRO); Microbiologist, NCFST. AACR Associate Member; editor or peer reviewer for six journals. U.S. Permanent Resident.

SELECTED PUBLICATIONS

- Tailored CD4+ lymphocytes expressing human CHAT protein as a novel vasodilator in attenuating RV pressure in a PAH animal model. Translational Research, 2025. (First author)
 - Deficiency of the deubiquitinase UCHL1 attenuates pulmonary arterial hypertension. Circulation, 2024. (Co-first author)
 - IL-18 mediates sickle cell cardiomyopathy and ventricular arrhythmias. Blood, 2021. (First author)
- 22 peer-reviewed publications, approximately 450 citations, four appearing in 2025, plus 25+ national meeting abstracts. Full record: NCBI bibliography, ORCID 0000-0001-7305-055X, Google Scholar.

COMPANY INFORMATION

Legal name Star Biopharma Solutions LLC **Type** Small business, Arizona LLC **NAICS** 541714, 541715, 541690
Engagements Hourly advisory, fixed-scope project, or monthly retainer **Principal** Akash Gupta, Ph.D.

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