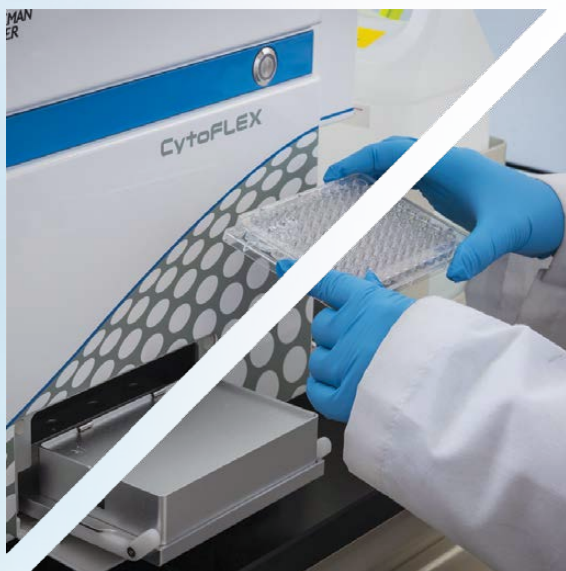


CAR-T Cell Therapy

Pharmaron delivers end to end preclinical support to advance your CAR-T candidate to IND-or IMPD-readiness for First-in-Human (FIH) trials. Our global team of cell and gene therapy experts brings deep experience in designing tailored testing strategies that reflect the unique biology and complexity of each CAR-T therapy, ensuring a scientifically rigorous and efficient path to the clinic.



Services:

Bioanalysis

- Cytokine analysis by MSD
- CAR transgene analysis by ddPCR
- Flow cytometry for T cell profiling
- Off-the-shelf qPCR method for human ALU
- Preclinical and clinical bioanalysis (Non-GLP/GLP/CLIA)

Immunogenicity

- Risk-based immunogenicity assessment for cells, transgenes, vectors, and impurities
- Humoral and cellular immune response

Pharmacology & Safety Assessment

- Non-GLP PK/PD (CAR-T cell generation, activation, proliferation, engraftment, clearance)
- GLP IND-Enabling toxicology
- CDX tumor-bearing mice
- Humanization with PBMCs or irradiation
- Integrated cell culture, flow, and IVIS imaging
- Viral shedding (for *in vivo* CAR VV delivery)

Analytical CMC

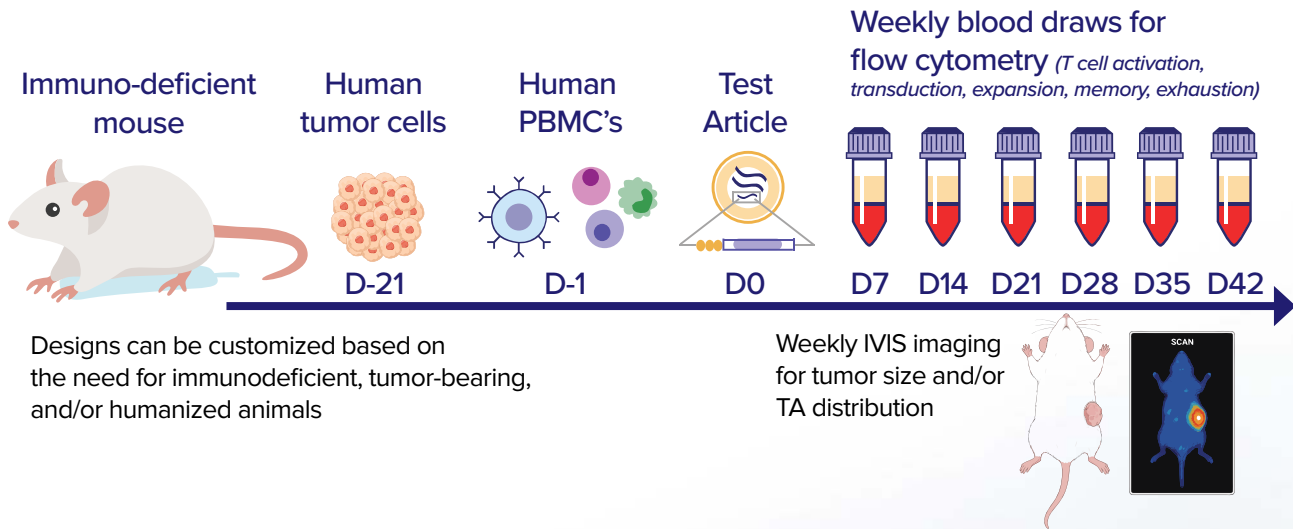
- GMP compliant facilities
- Bespoke potency assay development
- Cytotoxicity assays (Flow & reporter plate-based)
- Multiplex cytokine profiling (Ella/MSD)
- VCN quantification (qPCR/ddPCR/dPCR)
- Cytokine-independent growth assay

- Efficacy:**
- *In vitro* cytotoxicity, cytokine production, and antigen-specific targeting
 - *In vivo* tumor regression in CDX tumor models

- Safety:**
- *In vivo* cytokine release, neurotoxicity, on-target/off-tumor effects, vector integration, and uncontrolled proliferation
 - GLP IND-enabling toxicology studies

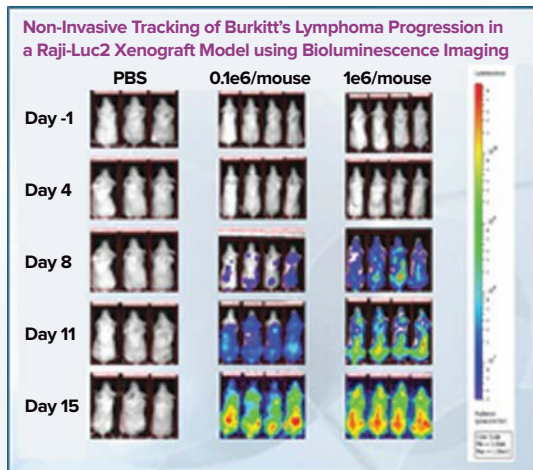
- PK/PD:**
- Engraftment, expansion, biodistribution, persistence, and clearance
 - Cytokine production, tumor killing, T cell activation/exhaustion

Example Study Design: *In Vivo* CAR-T in Tumor Bearing Mice



Designs can be customized based on the need for immunodeficient, tumor-bearing, and/or humanized animals

Live Animal IVIS Imaging



Study Endpoints & Bioanalysis

- Cytokine measurement by MSD
- CAR transgene distribution by ddPCR
- Viral shedding and clearance by RT-qPCR
- Histopathology – H&E on full tissue list
- Clinical Pathology
- IHC biomarkers
- Custom and off-the-shelf methods for test article and biomarkers



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