

Here is the project blueprint for the mechanical oncology initiative, based on the master R&D plan (*HEMPOXY MECHANICAL ONCOLOGY PLATFORM Master Research & Development Plan v1.0*, authored by Marie-Soleil Seshat Landry, CEO of Landry Industries & Marie Landry Spy Shop):

HEMPOXY MECHANICAL ONCOLOGY PLATFORM

Master Research & Development Plan (Phases I–IV)

1. Executive Summary & Core Objective

- **Problem Statement:** Conventional oncology relies primarily on chemical and biological pathways that face severe limitations due to cellular resistance mechanisms and systemic toxicity.
- **Proposed Solution:** A non-chemical, physical approach utilizing engineered microneedles/nanostructures (fabricated from hemp-fiber reinforced epoxy composites, "Hempoxies") guided by AI-driven real-time targeting to physically disrupt malignant cell membranes (mechanical lysis).

2. Phase Breakdown & Timeline

Phase I: Material Characterization & Formulation (Months 1–3)

- **Task 1.1: Hempoxy Tensile Strength Validation (Weeks 1–4):** Formulating and testing ASTM D638-Type IV specimens to confirm the required structural integrity, tensile strength, and tuning capabilities of the composite matrix.
- **Task 1.2: Microneedle Fabrication & Mechanical Characterization (Weeks 3–8):** Developing micro-scale structures optimized for membrane puncturing without premature structural failure.
- **Task 1.3: Chitosan Debris Binding Kinetics (Weeks 4–12):** Assessing binding kinetics to manage and neutralize cellular debris post-lysis.
- **Task 1.4: Biocompatibility Assessment (Weeks 6–12):** Performing initial viability and safety assays on the material components.

Phase II: Tumor-on-Chip Integration & Efficacy Validation (Months 4–6)

- **Task 2.1: Tumor-on-Chip Device Design & Fabrication (Weeks 4–8):** Constructing Polydimethylsiloxane (PDMS) microfluidic testbeds for controlled experimentation.
- **Task 2.2: Tumor Spheroid Preparation & Integration (Weeks 6–9):** Culturing and embedding 3D tumor spheroids into the microfluidic architecture.
- **Task 2.3: Mechanical Lysis Protocol & Real-Time Monitoring (Weeks 8–10):** Executing controlled mechanical destruction combined with Electrical Impedance

Spectroscopy (EIS) and microscopy documentation.

- **Task 2.4: Selectivity Assessment (Weeks 9–12):** Evaluating differential impact profiles between malignant cell lines and healthy tissue controls.
- **Task 2.5: Cytokine Profiling & Tumor Lysis Syndrome (TLS) Prevention (Weeks 10–13):** Monitoring biomarker release thresholds to prevent acute TLS responses during lysis.

Phase III: AI Targeting & Optimization (Months 7–12)

- **Task 3.1: Feature Engineering & Data Acquisition (Weeks 13–16):** Extracting impedance-based feature sets from real-time testing data.
- **Task 3.2: Machine Learning Model Development (Weeks 16–20):** Training and evaluating predictive classification models to distinguish malignant states via electrical signatures.
- **Task 3.3: Real-Time Targeting Algorithm & Integration (Weeks 20–24):** Deploying rolling-wave activation patterns and hardware-software integration for automated precision control.
- **Task 3.4: Validation on 3D Spheroid Co-Cultures (Weeks 21–24):** Testing algorithmic selectivity and destruction efficiency in complex co-culture environments.

Phase IV: Preclinical Efficacy In Vivo (Months 13–18)

- **Task 4.1: Xenograft Tumor Model Development (Weeks 25–30):** Establishing in vivo models under strict regulatory and ethical compliance frameworks.
- **Task 4.2: Treatment Randomization & Efficacy Study (Weeks 30–42):** Executing longitudinal treatment protocols measuring primary tumor volume reduction and secondary survival endpoints.
- **Task 4.3: TLS Biomarker & Safety Monitoring (Weeks 30–42):** Continuous blood sampling and serum marker analysis throughout the active intervention window.
- **Task 4.4: Histopathology & Organ Toxicity Assessment (Week 42):** Conducting terminal necropsies and histological evaluations to confirm systemic safety and zero off-target organ damage.

3. Strategic Outputs & Roadmap

- **Publication Strategy:** Phased rollout spanning materials science journals (Month 6), bioengineering platforms (Month 10), AI/biomedical computing (Month 16), and clinical oncology (Month 22).
- **Intellectual Property:** Core patent filings covering the hemp-epoxy structural formulations, micro-array mechanical lysis geometries, and AI-driven impedance targeting systems.