Clinical Trial Budget Estimate: ImmunoFolate for ARDS (Phase 2)

Trial Size: 100 patients
Design: Double-blind, placebo-controlled
Duration: 12 months (6–9 months enrollment + 3 months follow-up/reporting)
Sites: 3–5 hospitals with ICU enrollment capacity

Category	Estimated Cost (USD)	Notes
1. Site Costs		
Site start-up fees (IRB, contracting)	$75,000	$15K/site × 5 sites
Per-patient payments	$750,000	$7,500/patient average (screening, treatment, follow-up)
Site monitoring (CRA)	$120,000	~$2,000/monitoring visit × 60 visits
Subtotal Site Costs	**$945,000**	

2. Clinical Supplies		
ImmunoFolate production (GMP)	$150,000	Includes formulation, QC, packaging (pilot GMP run)
Placebo production	$50,000	Matched formulation and blinding
Labeling, storage, distribution	$25,000	Central pharmacy and shipping to sites
Subtotal Clinical Supplies	**$225,000**	

3. Central Services		
Central lab tests (cytokines, CRP, safety labs)	$120,000	$1,200/patient × 100
Imaging (CXR/CT if protocol-mandated)	$60,000	If required; can be standard-of-care
Electronic data capture (EDC) system	$45,000	Includes setup, licenses, hosting
Randomization/IWRS system	$25,000	Interactive web response system for blinding
Data management and biostatistics	$85,000	Database cleaning, analysis, reporting
Medical writing and CSR	$30,000	Clinical Study Report preparation
Subtotal Central Services	**$365,000**	

4. Regulatory & Oversight		
IND preparation and maintenance	$40,000	Includes pre-IND briefing, annual updates
Independent DSMB	$30,000	Quarterly safety review meetings
QA/QC audits	$15,000	1–2 audits total
IRB central fees	$15,000	Optional centralized IRB
Subtotal Regulatory	**$100,000**	

5. Project Management and Overhead		
Project manager (0.5–1.0 FTE)	$120,000	12 months @ ~$10K/mo
Sponsor oversight (internal team or CRO)	$60,000	Travel, meetings, oversight

Insurance (clinical trial liability)	$25,000	Industry average premium
Contingency (10%)	$180,000	Buffer for unexpected costs
Subtotal Management & Overhead	**$385,000**	

✅ Total Estimated Budget: $2,020,000

Optional Add-Ons (if needed):

- **Pharmacokinetic study sub-cohort:** +$100,000
- **Biobanking of patient samples:** +$50,000
- **Patient travel reimbursement:** +$20,000
- **Expanded number of sites (e.g., 10):** +$300,000