Here's a draft **budget estimate** for the clinical trial titled:
**“Efficacy and Safety of Immunofolate in Combination with PD-1 Inhibitors in Advanced Non-Small Cell Lung Cancer”**

This estimate is for a **Phase II**, **randomized controlled trial** with **150 patients** (75 per arm) over a **2-year** timeline. The budget may vary depending on geographic region, sponsor type (academic vs. industry), and CRO involvement, but the following gives a comprehensive overview.

**🧾 Clinical Trial Budget Estimate (USD)**

| **Category** | **Cost (USD)** | **Notes** |
| --- | --- | --- |
| **1. Study Start-Up Costs** | **$500,000** |  |
| - Protocol development, IRB/ethics submissions | $150,000 | Includes regulatory support |
| - Site selection and initiation (10–15 sites) | $200,000 | Site qualification visits, SIVs |
| - Contracts/legal | $50,000 |  |
| - Investigator’s meetings & training | $100,000 | Travel + coordination |

| **2. Patient Recruitment & Retention** | **$1,200,000** | | | - Recruitment advertising + pre-screening | $300,000 | Outreach campaigns, registries | | - Patient travel reimbursements | $150,000 | $1,000 per patient | | - Site recruitment bonuses | $750,000 | $5,000/patient at 150 patients |

| **3. Per-Patient Costs (Direct Costs)** | **$4,200,000** | | | - Immunofolate supply (experimental arm) | $600,000 | Estimated $8,000 per patient × 75 | | - PD-1 inhibitor (cost offset by standard of care or sponsor) | Covered separately | If not provided, can be $100k+ per patient | | - Site payments (procedures, labs, visits, imaging) | $3,000,000 | Avg. $20,000 per patient | | - Adverse event management/rescue meds | $600,000 | Includes monitoring of irAEs |

| **4. Laboratory, Biomarkers & Correlatives** | **$900,000** | | | - PD-L1, TMB, immune profiling, cytokines | $600,000 | ~ $4,000 per patient × 150 | | - Biobanking (blood/tissue storage) | $150,000 | | | - Central lab and shipping | $150,000 | |

| **5. Data Management & Monitoring** | **$1,200,000** | | | - Electronic Data Capture (EDC) | $300,000 | Includes setup & licenses | | - On-site monitoring / CRA costs | $600,000 | ~$4,000 per patient | | - Data cleaning, query resolution | $300,000 | Includes mid-study updates |

| **6. Safety & Regulatory Oversight** | **$450,000** | | | - DSMB meetings and safety reviews | $150,000 | Interim reviews every 6 months | | - SAE reporting / pharmacovigilance | $300,000 | |

| **7. Statistical Analysis & Reporting** | **$250,000** | | | - Biostatistics support (interim + final) | $150,000 | | | - Medical writing (CSR, publications) | $100,000 | |

| **8. Project Management (10-15% of total)** | **$850,000** | Full-time PM and trial coordination |

| **9. Contingency (~10%)** | **$750,000** | For unexpected costs and overruns |

**💰 Total Estimated Budget: $10,300,000**