

Prospective Trials

Trial Protocols

Pre-specified hypotheses and endpoints. Registered in clinicaltrials.gov

Endpoint Selection

Diagnostic accuracy vs clinical outcomes. Hard outcomes (mortality) vs surrogate markers

Sample Size

Power analysis for adequate statistical power. Account for prevalence and effect size

Randomization

AI-assisted vs standard of care. Cluster randomization by site to avoid contamination

Analysis Plans

Pre-specified statistical analysis. ITT vs per-protocol analysis