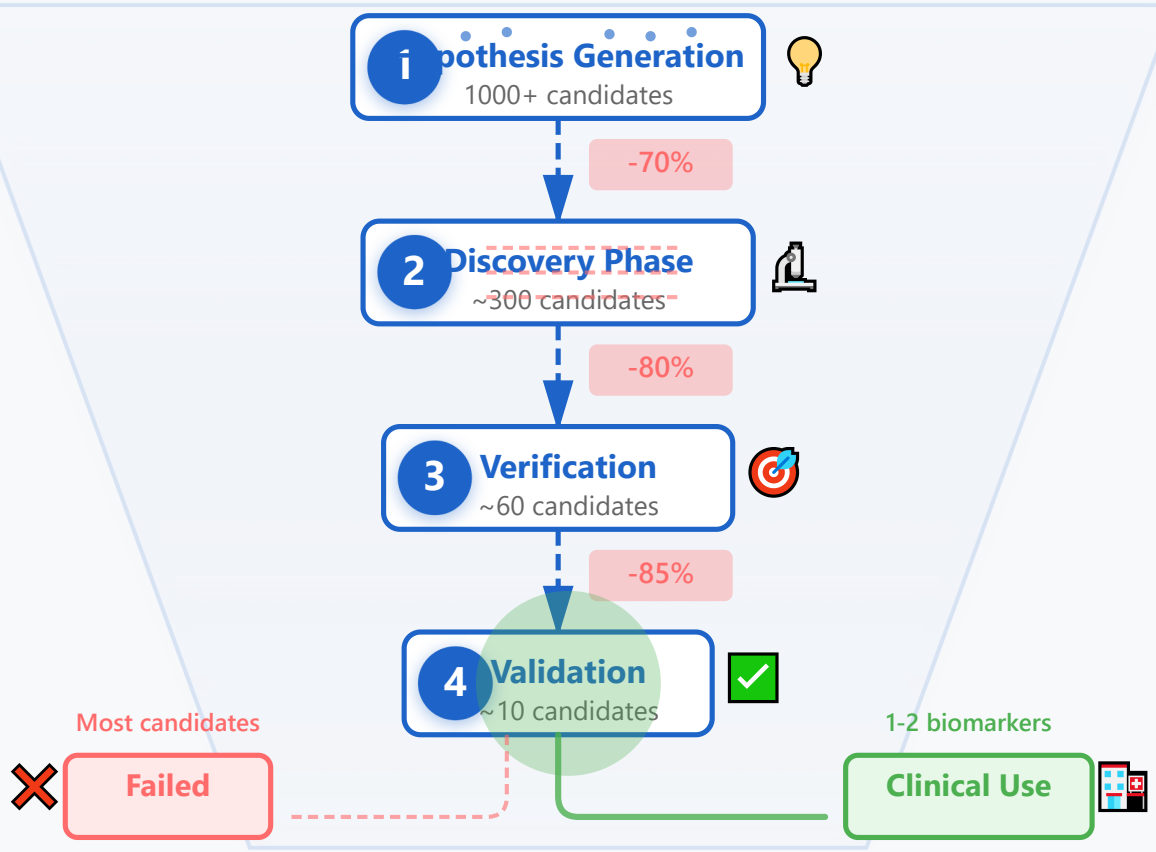
Discovery Pipeline

Biomarker Development Process from Hypothesis to Clinical Implementation



Data Sources:

Literature
Data Mining
Omics Studies

Study Design:

Prospective
Studies
RCTs

⚠ High attrition rate - most candidates fail before reaching clinical implementation

Detailed Description and Examples for Each Stage

1 Hypothesis Generation
Initial Discovery Stage

Objective: Identify as many potential biomarker candidates as possible

Key Activities

- Literature review and meta-analysis
- Re-analysis of existing omics data
- Biological pathway analysis
- Expert consultation

Specific Example

In Alzheimer's disease research, approximately 1000 cerebrospinal fluid

2 Discovery Phase
Initial Screening Stage

Objective: Select promising candidates through initial screening

Key Activities

- High-throughput screening
- Small-scale case-control studies
- Statistical significance assessment
- Biological plausibility validation

Specific Example

Measuring and comparing concentrations of 300 proteins in blood samples from 50 cancer patients vs 50 healthy controls

3 Verification
Reproducibility Confirmation

Objective: Confirm reproducibility in independent samples

Key Activities

- Independent cohort studies
- Targeted quantitative analysis
- Sensitivity/specificity evaluation
- Validation in diverse patient populations

Specific Example

Multicenter study validating diagnostic accuracy of 60 selected biomarkers in 200 patients

proteins identified as candidate biomarkers

4 Validation

Clinical Utility Confirmation

Objective: Final confirmation of clinical utility and practicality

✅ Key Activities

- Prospective clinical trials
- Randomized controlled trials (RCTs)
- Clinical utility assessment
- Cost-effectiveness analysis

💡 Specific Example

Prospective study with 1000 patients demonstrating clinical value of 2-3 final selected biomarkers

Key Statistics

1000+	~99%	1-2	5-10 yrs
Initial Candidates	Overall Attrition Rate	Final Approved Biomarkers	Average Development Time