The Road to Drug Discovery

Choose "Target" Disease
Choose Cellular Target

Compound Library

Bioassay

Lead Modification
Chemical Synthesis of Analogs

Bioassay

LEAD COMPOUND

Folk Medicine
or
Accidental Discovery

LEAD COMPOUND

2 or 3 preclinical candidates

• Drug Metabolism and Pharmacokinetics (DMPK)
• Efficacy and high-dose toxicity in two animal models
• Process Chemistry Scale up Synthesis (Kilograms)

Phase 1: toxicity, metabolite ID
20-50 volunteers, ~1 year

Phase 2: formulation, dose-ranging studies
clinical proof-of-concept,
20-100 patients, 1-4 years

Phase 3: efficacy, detn product advantages,
3-5 years
100's-1000's of patients

Phase 1, 2, and 3 Clinical Trials in Humans

FDA Approval

Phase 4: safety and efficacy in general public

Begin search for "Second Generation"
drug to improve drug and/or extend patent protection