





# RH Bouchard & Associates

- ◆ BioPharma/Clinical  
Research Consulting

Strategic Clinical Outsourcing Conference

Evaluating Your Core Competencies



# Panelists

- ◆ Rikki Bouchard, MPA
  - President, RH Bouchard & Associates, Inc.
- ◆ Andrew Denker, MD, PhD
  - Director of Clinical Pharmacology, MERCK
- ◆ Jim Kirwin, MBA
  - Assistant Vice President, WYETH Research
- ◆ Arnaud Partiot, PhD
  - Senior Vice President, Research & Development, SHIRE Pharmaceuticals
- ◆ Jay Turpen
  - Director Medical Sourcing Capabilities, ELI LILLY & Co.
- ◆ Nancy Widener
  - Global Director Investigator Contracts & Outsourcing Management, BRISTOL-MYERS SQUIBB



# Definition Core Competency

- ◆ Core: A central and often foundational part distinct from the enveloping part, a central strand around which other strands twist
- ◆ Competent: Having requisite or adequate abilities, having the capacity to function in a given way



# What Gets Outsourced?

- ◆ Functions
  - Data management, stats, medical writing
  - Investigator Contracts & Payments, Reg Doc processing
  - Safety Reporting
  - Clinical Monitoring
  - QA
- ◆ Therapeutic Programs
  - In-licensed or new therapeutic area
- ◆ Phases
  - Phase I
  - Post-marketing



# Why Outsource?

- ◆ Flexibility
- ◆ Access to expertise
- ◆ Cost Containment
- ◆ Access to new technology w/o investment
- ◆ Resource management



# How to decide?

- ◆ Review and assessment of internal expertise
  - Scientific
  - Regulatory
  - Therapeutic
  - Operational
- ◆ Outsourcing Strategy must be based on Development Strategy