

# FORUM ON NEUROSCIENCE AND NERVOUS SYSTEM DISORDERS

## Multimodal Therapies for Brain Disorders: A Workshop

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**Mode-** A manner of acting or doing; method; way  
**Multimodal-** Having more than one mode

### Potential Therapeutic Multi-Modes

Combinations from the following:

- Drugs
- Biologics
- Devices
- Behavioral interventions
  - Physical Therapy
  - Exercise
  - Psychotherapy
  - Cognitive/Behavioral Therapy

### Potential Guidance:

Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes 3/16

Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products 7/13

Codevelopment of Two or More New Investigational Drugs for Use in Combination 6/13

Early Development Considerations for Innovative Combination Products 9/06

# Potential advantages and issues in multimodal therapy

## An attempt to improve efficacy in brain disorders

### Potential Advantages

- Additive effects -  $1+1=2$
- Synergistic effects -  $1+1=3$
- 'Super' synergy -  $0+1=5$ 
  - eg carbidopa + levodopa

### Potential Issues:

Differing time profiles of the benefits

Differing time profiles of risks

Assessing dosage in devices

Assessing dosage with behavioral interventions

Conflicting regulatory standards