

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