

# Regulatory Discussion

## Agitation in Alzheimer's Disease

### FDA Perspective

Tiffany R Farchione, MD  
Deputy Director  
Division of Psychiatry Products  
Center for Drug Evaluation and Research

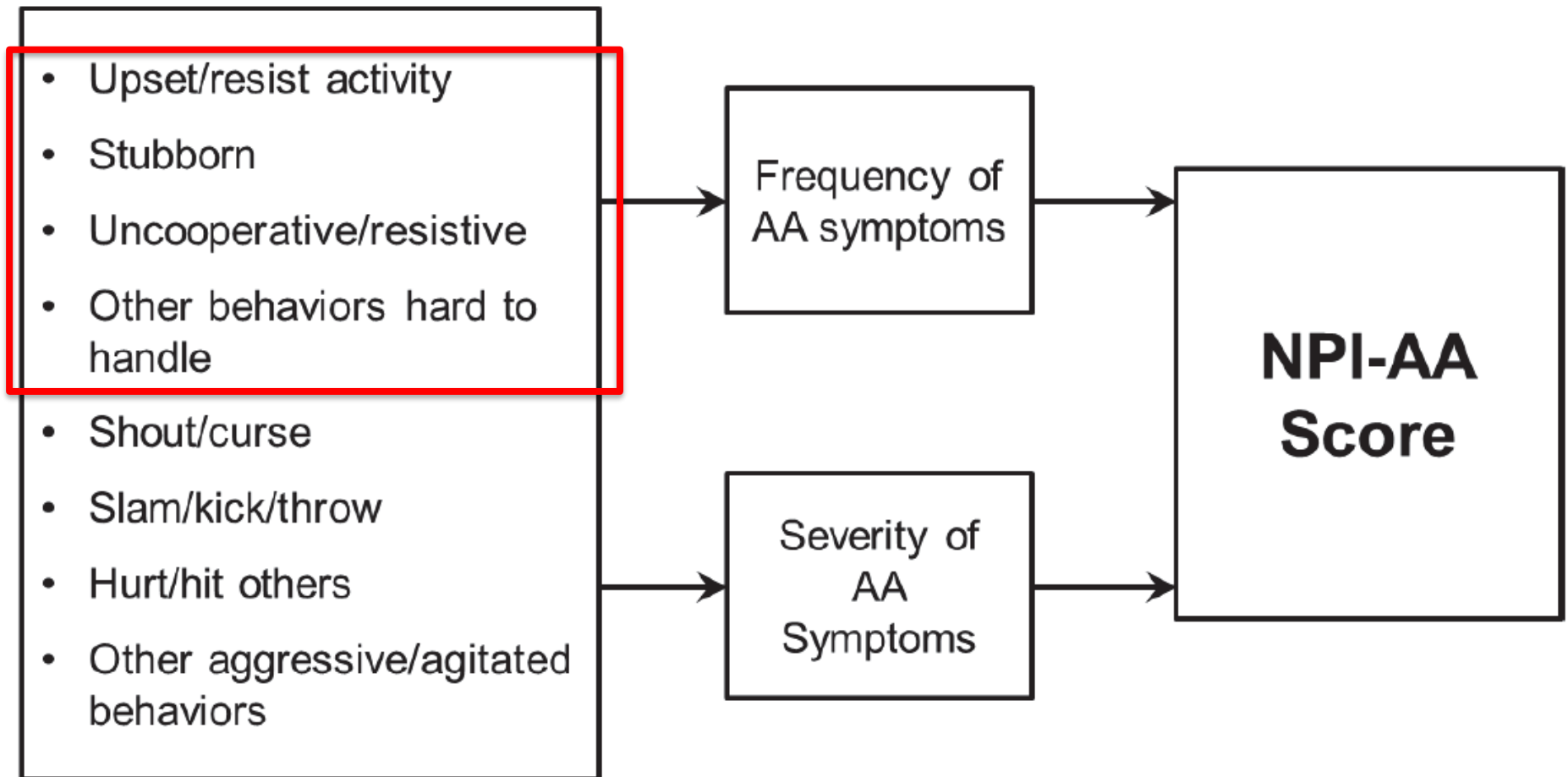
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Pseudonymity

# Non-Pharmacologic Intervention

- Stage of development important
- Defining population for whom the drug will be beneficial
- Labeling considerations

# Defining the Concept of Interest



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- CMAI
  - Subscales should be rated separately
  - Not intended for a total score (per user manual)
- NPI-C
  - Don't combine agitation and aggression
    - Weighted toward agitation
    - Why stubbornness? Hoarding/hiding objects?
    - Sensitivity to change is unknown

# Caregiver Burden

- Agree that it's important
- BUT...not a direct benefit to the patient
- Need to know that patient is not just sedated

# Useful for Any Endpoint

- Engage us early
  - Submit rater training materials, scoring instructions, evidence of reliability/validity/sensitivity to change
  - Responder definition is helpful
    - Can use Phase 2 data to inform definition to be used in Phase 3

