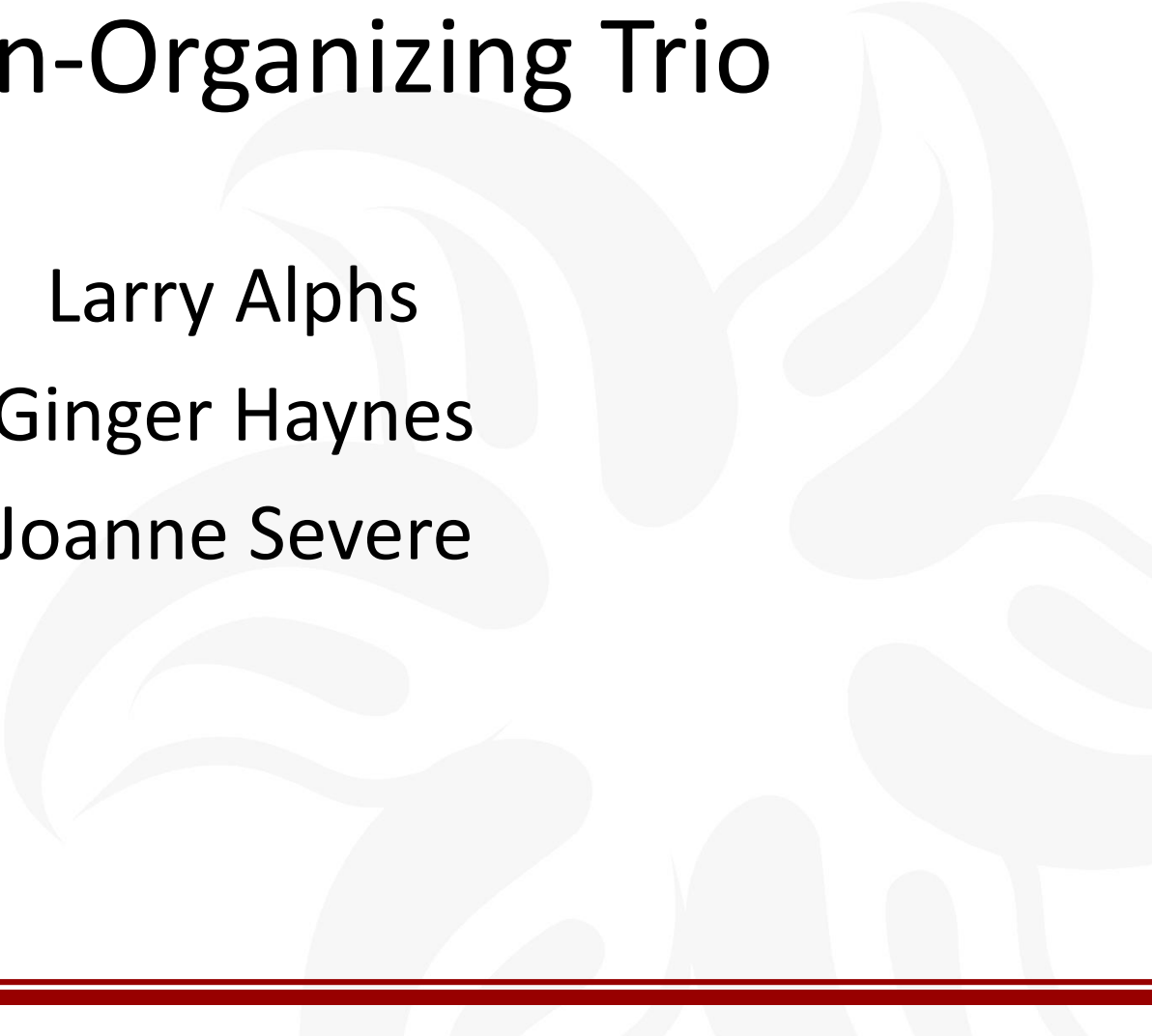


Forming and Utilizing Integrated Clinical Trials Databases

To Advance Insights in Treatments
for Cognition in
Schizophrenia and Alzheimer's Disease

Session-Organizing Trio

Larry Alphas
Ginger Haynes
Joanne Severe



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Treatments for Cognition in
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What this session is NOT About:

- Not “Big Data”
 - Not Same Patients in different data domains
 - Not traditional “meta-analyses”
-

What this session IS about:

One database formed from

- Patient-level data (on different patients)
- Multiple, independent clinical trials

Requires

- Sharing
 - Access
-

WHY Create Integrated Databases

- Powerful tool
 - Large, Heterogeneous
 - Allow moderator analyses
 - Explore signals
 - Inform design of new and more effective trials
-

I. DoCTRS Integrated Database

Til Wykes and Sarah Morris

- Cognitive Remediation trials in schizophrenia
 - Independent researchers shared databases
 - NIMH-sponsored
 - Trials and Tribulations
-

II. Clinical Trial Simulation Tool

Klaus Romero and Vikram Sinha

- Alzheimer's Disease
 - Pharma companies shared databases
 - FDA and EMA participation in development
 - Goals and accomplishments
-

III. Statistical and Methodological Challenges and Solutions

Eugenio Andraca-Carrera

- Example using integrated database outside of CNS field
 - Types of questions addressed
 - Statistical approaches
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Goals of Session

- Foster dialogue about maximizing power of existing clinical trial databases by sharing and forming integrated databases
 - Begin to understand challenges and solutions in forming and using integrated databases
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