Neurocognitive Outcomes Working Group
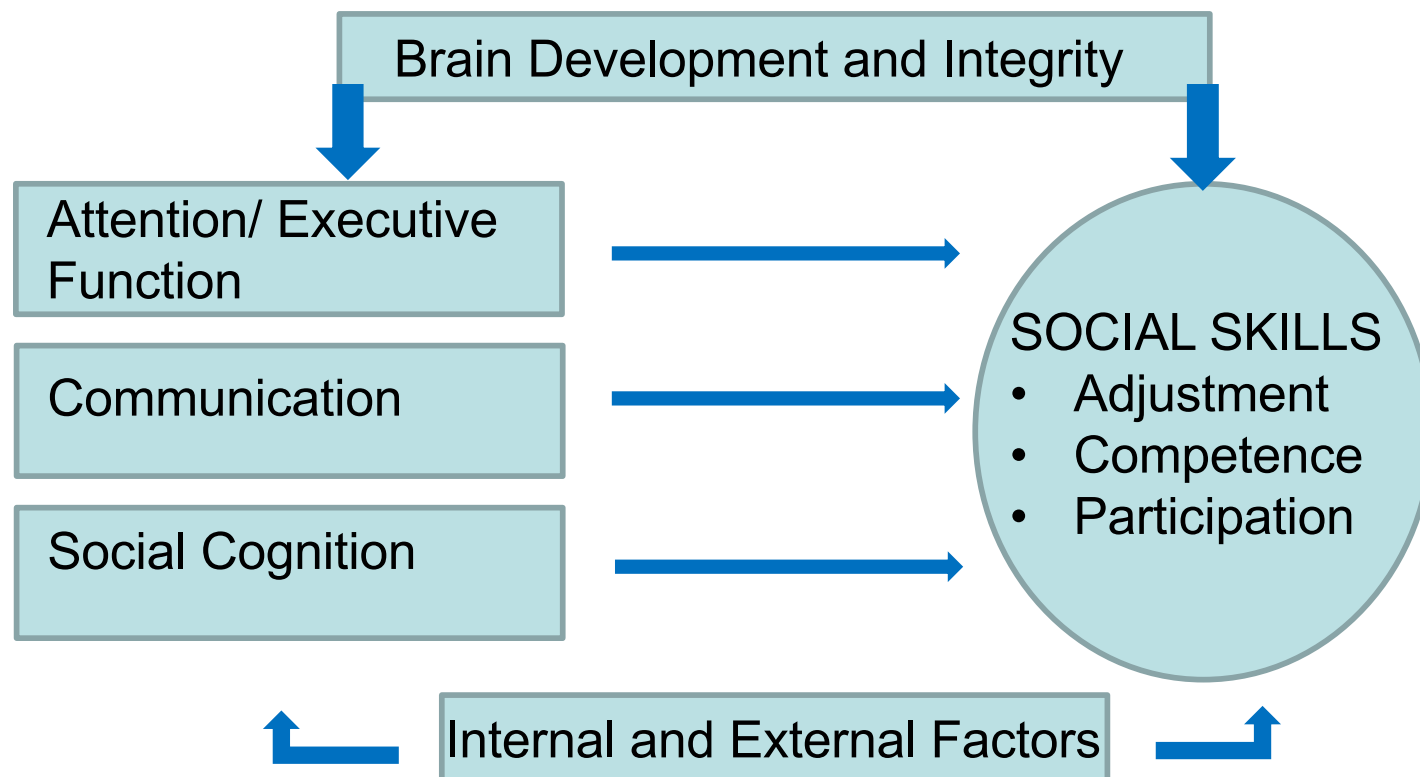
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Children's Hospital Colorado

Response **E**valuation **I**n **N**eurofibromatosis **S**chwannomatosis
INTERNATIONAL COLLABORATION

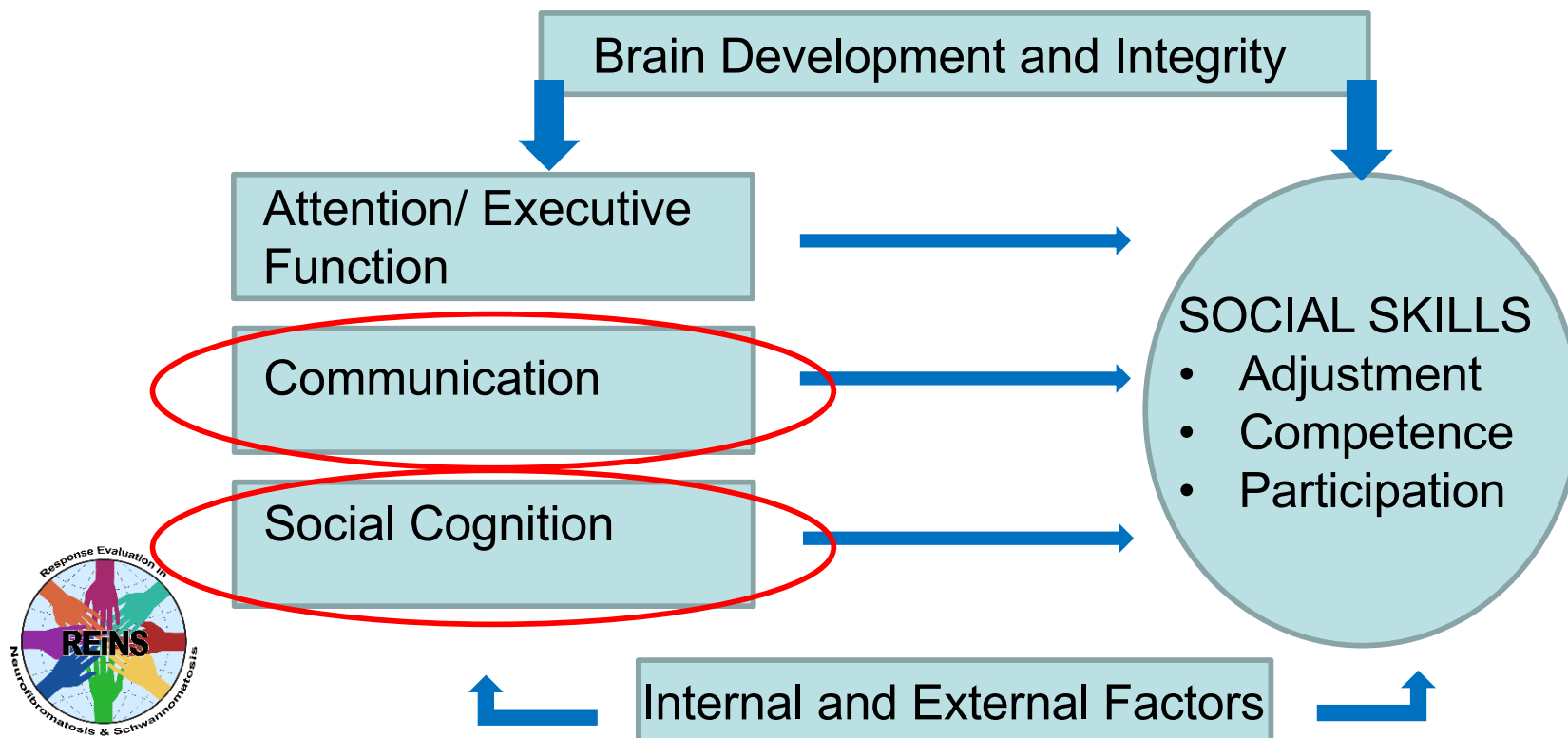# Current Focus- Measures of Social Skills

- Social skills are complex

- Theoretical model
  - <u>So</u>cio-<u>C</u>ognitive <u>I</u>ntegration of <u>A</u>bilities Mode<u>l</u> (SOCIAL; Anderson and Beauchamp)

Brain Development and Integrity

Attention/ Executive Function	→	
Communication	→	SOCIAL SKILLS • Adjustment • Competence • Participation
Social Cognition	→	

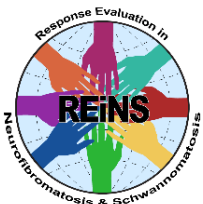| Internal and External Factors |
|---|

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- Theoretical model
  - <u>So</u>cio-<u>C</u>ognitive <u>I</u>ntegration of <u>A</u>bilities Mode<u>l</u> (SOCIAL; Anderson and Beauchamp)

Frequently Used Measures

- Social Communication Questionnaire
- Social Skills Questionnaire
- Autism Social Skills Profile
- Profile of Social Difficulty
- Social Skills Checklist
- Socialization scale, Vineland Adaptive Behavior Assessment System
- Social Competence Questionnaire
- Social Skills Rating System/ Social Skills Improvement System
- Social Responsiveness Scale-2
- Children's Communication Checklist-2

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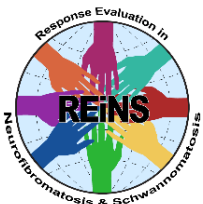
COGRATE: COGnitive outcomes Rating Acceptance Tool for Endpoints

Domain: ☑ Executive Function   ☐ Attention   ☐ Processing Speed

Measure:

Rater: Date: ___/___/_____

RATINGS

3=Solid data and published information supporting its use in NF
2=Good preliminary data and relevant information but needs more work
1=Limited data but information suggests potential
0=No/poor data/information
 *Half ratings (.5, 1.5, 2.5) can be used if needed

Rating Criteria	Rating (0-3): use in NF trials
1. Patient characteristics: Age range (e.g., child, adolescent, adult) Normative groups (e.g., general, NF, oncology, other, # subjects)	
2. Used in published studies: Number and types of studies (e.g., descriptive, clinical trials)	
3. Test appropriateness for clinical trials endpoint: Test specificity/purity (how pure is the measure to the domain/skill it is developed to measure?) Test targets one or more of the known or future endpoints for NF clinical trials directly	
4. Scores available: Types of scores available (e.g., raw, standardized, domain, total; gaps in normative data)	
5. Psychometric Data: Reliability (e.g., internal consistency, test/retest) Validity (e.g., construct, discriminative) Factor analysis Practice Effects/Availability of Alternate Forms/Time between testing information	
6. Feasibility:	

Cost (for test instrument, protocols, and scoring)	
Length (time to administer/complete)	
Ease of administration/challenges to administration	
Qualifications to administer test (level of training)	
Appropriateness for alternative testing settings (e.g., clinic, etc.)	
Other languages available	

Overall Impression for use in NF Clinical Trials (Pros/Cons) – Is the measure a critical Primary Outcome Measure?:	Total (mean):

Level of Acceptance (Committee Decision):
___ Primary outcome measure
___ Secondary outcome measure
___ Not acceptable at this time/further information needed (specify)
___ Not acceptable (no further review)

Committee Notes/Comments:

One Page
Multiple Pages
Page Width
Zoom
100%
Zoom
New Window
Arrange All
Split
View Side by Side
Synchronous Scrolling
Reset Window Position
Window
Switch Windows
Macros
Macros

COGRATE: COGnitive outcomes Rating Acceptance Tool for Endpoints

Patient Representative Form

Measure:	
Rater:	Date:____/____/_____

RATING ANCHORS

3 = Strongly Agree
2 = Agree
1 = Disagree
0 = Strongly Disagree

Rating Criteria *Please complete this section prior to the phone call*	Rating 0-3
Feasibility	
• Directions are easy to understand. Would you be able to complete this questionnaire if given it with no other explanation? (for example, how to fill out the form; time period to consider when rating)	
• Scale for responses is easy to understand	
• Questions are easy to understand	
• How long does it take to complete this test? ____ This is a reasonable amount of time	
• This questionnaire is relevant to an area of difficulty for people with NF1	
MEAN RATING	

RATING ANCHORS

3 = Good convincing data and published information supporting the tool's use in NF
2 = Good preliminary/early data and relevant information but needs more work
1 = Limited data but information suggests potential
0 = No data/poor data/information
 *Half ratings (.5, 1.5, 2.5) can be used if needed*

Rating Criteria *This section can be completed during phone call based on group discussion*	Rating (0-3): for use in NF trials
1. Patient characteristics: What is the age range that the tool can be used (e.g., child, adolescent, adult)? Is there information/data on how individuals with diseases such as NF perform on the tool/test? Yes No If yes, which groups?	
2. Used in published studies: How many studies have been published using this tool (overall)? How many were clinical trials (a study with some type of intervention)? What age span was included in the published trials? How many published studies included individuals with NF?	
3. Test appropriateness for clinical trials endpoint: Does this tool test areas of learning, behavior, or cognition that are relevant to NF research? Do you think that the tool is important for future cognitive research in NF? Yes No	
Overall Impression for use in NF Clinical Trials (Pros/Cons) – Is the measure an acceptable outcome measure based on your review and committee discussion?	Total (mean):

Notes/Comments:

Preschool Subcommittee Attention Measure Review

- Reviewed clinic-based attention measures (eg, DAS-II digits forward task)

- Reviewed computerized assessments of attention and emerging executive functioning for use in young children (eg, CogState, NIH Toolbox, CANTAB, K-CPT, TOVA, Gordon)

- Reviewed broad psychosocial measures that include attention (BASC, Achenbach)

- Next on agenda: Targeted attention/EF questionnaire measures (BRIEF-P)
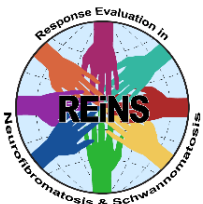
Future Directions for Preschool Work

- Need for more data about psychometric properties of measures with young children with NF1 (ie, disease-specific normative data)

- Development of best practice guidelines for including young children with NF1 in clinical trials

- Consideration of recommendations in other domains
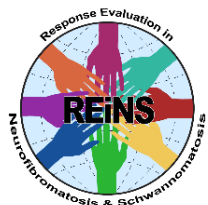
Neurocognitive Committee

- Jennifer Janusz (Chair)
- Karin Walsh
- Kristina Hardy
- Pam Wolters
- Staci Martin
- Bonnie Klein-Tasman
- Jonathan Payne
- Nicky Ullrich
- Peter deBlank
- Heather Thompson
- Mary Anne Tamula
- Tess Kennedy
- Stephanie Malarbi

- Claire Semerjian
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