

## **Appendix 3**

### **ADCS-CGIC Scale (Report Forms)**

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

BASELINE Examination - ADCS - CGIC Page 1 of 5

**Baseline Visit**

<b>Subject ID and Initials:</b> _____ Examiner _____	
Examination Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <small>Month Day Year</small>	Time of day interview started: _____ (24 hour clock)

**Brief Instructions:** See instruction sheet. Use this form to record baseline information for assessing change at a later date. Refer to the cover page for instructions on obtaining relevant information. A brief clinical assessment of mental state should be made. No particular format or order is suggested for the interview.

Area	Probes	Notes
Relevant History	<ul style="list-style-type: none"> <li>recent relevant clinical events, illnesses?</li> </ul>	Patient    Caregiver
Observation/ Evaluation	<ul style="list-style-type: none"> <li>appearance</li> </ul>	Patient    Caregiver
<b>Mental/Cognitive State</b>		Structured exam, if used:
Arousal/ Alertness/ Attention/ Concentration	<ul style="list-style-type: none"> <li>confusion/clarity</li> <li>excitement/reactivity</li> <li>state of consciousness</li> </ul>	Subject    Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

**BASELINE Examination - ADCS - CGIC Page 2 of 5**

Area	Probes	Notes
Orientation	<ul style="list-style-type: none"> <li>• time</li> <li>• place</li> <li>• person</li> </ul>	Patient
		Caregiver
Memory	<ul style="list-style-type: none"> <li>• registration</li> <li>• recall</li> <li>• long term/remote</li> <li>• recall for past events</li> </ul>	Patient
		Caregiver
Language/Speech	<ul style="list-style-type: none"> <li>• fluency/ expressive language</li> <li>receptive language</li> <li>• comprehension</li> <li>• paraphasia/word finding</li> <li>• naming, amount</li> <li>• repetition</li> <li>• follows directions</li> </ul>	Patient
		Caregiver
Praxis	<ul style="list-style-type: none"> <li>• constructional ability</li> <li>• ideational praxis</li> <li>• ideomotor/imitation</li> </ul>	Patient
		Caregiver
Judgment/ Problem solving/ Insight	<ul style="list-style-type: none"> <li>• patient's behavior in situations requiring judgment</li> </ul>	Patient
		Caregiver



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**Clinical Global Impresssion of Change (CGIC)**

BASELINE Examination - ADCS - CGIC Page 3 of 5

Area	Probes	Notes
<b>Behavior</b>		
Thought content	<ul style="list-style-type: none"> <li>• organization</li> <li>• appropriateness</li> </ul>	Patient
		Caregiver
Hallucinations/ Delusions/ Illusions	<ul style="list-style-type: none"> <li>• auditory/visual</li> <li>• misperceptions</li> <li>• systematized/developed</li> </ul>	Patient
		Caregiver
Behavior/Mood	<ul style="list-style-type: none"> <li>• affect/lability</li> <li>• unusual/bizarre</li> <li>• uninhibited/sexually inappropriate</li> <li>• motivation/energy</li> <li>• wandering/getting lost</li> <li>• agitation/aggression</li> <li>• hostility</li> <li>• depression-related</li> <li>• anxiety-related</li> <li>• appropriateness</li> <li>• cooperativeness</li> <li>• demanding/dependent</li> </ul>	Patient
		Caregiver
Sleep/Appetite	<ul style="list-style-type: none"> <li>• sleep disorder</li> <li>• insomnia (type?)</li> <li>• nocturnal activity</li> <li>• hyper-, hyposomnia</li> <li>• appetite/weight change</li> </ul>	Patient
		Caregiver
Neurological/ Psychomotor activity	<ul style="list-style-type: none"> <li>• overall motor activity</li> <li>• posture/gait</li> <li>• movement disorder</li> <li>• unusual motor behavior</li> <li>• daily patterns</li> <li>• pacing</li> </ul>	Patient
		Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impresssion of Change (CGIC)**

BASELINE Examination - ADCS - CGIC Page 4 of 5

Area	Probes	Notes
<b>Functioning</b>		
Basic and complex (instrumental) functional ability	• mobility	Patient
	• hygiene/grooming	
	• dressing	Caregiver
	• self-feeding	
	• shopping	
	• household chores/hobbies	
	• finances	
• driving		
Social function	• participation in: - social interactions - community activities	Patient
	• independence	
	• helplessness	Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

BASELINE Examination - ADCS - CGIC Page 5 of 5

Notes, comments, summary statement:

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Information from other sources:

The following sources of information were used in completing this form:

- Interview/examination of patient
- Interview of caregiver. Describe relationship to patient: \_\_\_\_\_
- Information on neuropsychological test performance
- General information derived from a staff conference about the patient
- Other: \_\_\_\_\_



**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 1 of 5

**Week 7 visit**

<b>Subject ID and Initials:</b> _____ Examiner _____	Examination Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <small>Month Day Year</small>
Time of day interview started: _____ (24 hour clock)	

**Brief Instructions:** See instruction sheet. Use this form to record information for making a CGIC rating after interviewing both caregiver and patient. You may refer only to the Baseline Evaluation form. A brief clinical assessment of mental state should be made. No particular format or order is suggested for the interview.

Area	Probes	Notes
Relevant History	<ul style="list-style-type: none"> <li>• clinical events since baseline:</li> <li style="padding-left: 20px;">- changes?</li> <li style="padding-left: 20px;">- illnesses?</li> </ul>	Patient     Caregiver
Observation/ Evaluation	<ul style="list-style-type: none"> <li>• appearance</li> </ul>	Patient     Caregiver
<b>Mental/Cognitive State</b>		Structured exam. if used:
Arousal/ Alertness/ Attention/ Concentration	<ul style="list-style-type: none"> <li>• confusion/clarity</li> <li>• excitement/reactivity</li> <li>• state of consciousness</li> </ul>	Subject     Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

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Area	Probes	Notes
Orientation	<ul style="list-style-type: none"> <li>• time</li> <li>• place</li> <li>• person</li> <li>• time relationships</li> <li>• travel</li> <li>• find his/her way</li> <li>• recognises self/others/objects</li> <li>• reacts appropriately</li> </ul>	Patient
		Caregiver
Memory	<ul style="list-style-type: none"> <li>• registration</li> <li>• recall</li> <li>• long term/remote</li> <li>• recall for past events</li> </ul>	Patient
		Caregiver
Language/Speech	<ul style="list-style-type: none"> <li>• fluency/ expressive language</li> <li>receptive language</li> <li>• comprehension</li> <li>• paraphasia/word finding</li> <li>• naming, amount</li> <li>• repetition</li> <li>• follows directions</li> </ul>	Patient
		Caregiver
Praxis	<ul style="list-style-type: none"> <li>• constructional ability</li> <li>• ideational praxis</li> <li>• ideomotor/imitation</li> </ul>	Patient
		Caregiver
Judgment/ Problem solving/ Insight	<ul style="list-style-type: none"> <li>• patient's behavior in situations requiring judgment</li> </ul>	Patient
		Caregiver



**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 3 of 5

Area	Probes	Notes
<b>Behavior</b>		
Thought content	<ul style="list-style-type: none"> <li>• organization</li> <li>• appropriateness</li> <li>• hostile expression</li> </ul>	Patient
		Caregiver
Hallucinations/ Delusions/ Illusions	<ul style="list-style-type: none"> <li>• auditory/visual</li> <li>• misperceptions</li> <li>• systematized/developed</li> </ul>	Patient
		Caregiver
Behavior/Mood	<ul style="list-style-type: none"> <li>• affect/lability</li> <li>• unusual/bizarre</li> <li>• uninhibited/sexually inappropriate</li> <li>• motivation/energy</li> <li>• wandering/getting lost</li> <li>• agitation/aggression</li> <li>• hostility</li> <li>• depression-related</li> <li>• anxiety-related</li> <li>• appropriateness</li> <li>• cooperativeness</li> <li>• demanding/dependent</li> </ul>	Patient
		Caregiver
Sleep/Appetite	<ul style="list-style-type: none"> <li>• sleep disorder</li> <li>• insomnia (type?)</li> <li>• nocturnal activity</li> <li>• hyper-, hyposomnia</li> <li>• appetite/weight change</li> </ul>	Patient
		Caregiver
Neurological/ Psychomotor activity	<ul style="list-style-type: none"> <li>• overall motor activity</li> <li>• posture/gait</li> <li>• movement disorder</li> <li>• unusual motor behavior</li> <li>• daily patterns</li> <li>• pacing</li> </ul>	Patient
		Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 4 of 5

Area	Probes	Notes	
<b>Functioning</b>			
Basic and complex (instrumental) functional ability	<ul style="list-style-type: none"> <li>• mobility</li> <li>• hygiene/grooming</li> <li>• dressing</li> <li>• self-feeding</li> <li>• shopping</li> <li>• household chores/hobbies</li> <li>• finances</li> <li>• driving</li> </ul>	<p>Patient</p> <hr/> <p>Caregiver</p>	
	Social function	<ul style="list-style-type: none"> <li>• participation in: social interactions community activities</li> <li>• independence</li> <li>• helplessness</li> </ul>	<p>Patient</p> <hr/> <p>Caregiver</p>

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 5 of 5

Notes, comments, summary statement:

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Information from other sources:



**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change Rating**

**Week 7 visit**

**Subject ID and Initials:** \_\_\_\_\_  
Examiner \_\_\_\_\_ Examination Date   -   -    
Month Day Year

**Clinical Impression of Change from Baseline:**

- Marked improvement
- Moderate improvement
- Minimal improvement
- No change
- Minimal worsening
- Moderate worsening
- Marked worsening

Comments: \_\_\_\_\_  
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**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 1 of 5

**Week 12 visit**

<b>Subject ID and Initials:</b> _____ Examiner _____	Examination Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <small>Month Day Year</small>
Time of day interview started: _____ (24 hour clock)	

**Brief Instructions:** See instruction sheet. Use this form to record information for making a CGIC rating after interviewing both caregiver and patient. You may refer only to the Baseline Evaluation form. A brief clinical assessment of mental state should be made. No particular format or order is suggested for the interview.

Area	Probes	Notes
Relevant History	<ul style="list-style-type: none"> <li>• clinical events since baseline:</li> <li style="padding-left: 20px;">- changes?</li> <li style="padding-left: 20px;">- illnesses?</li> </ul>	Patient     Caregiver
Observation/ Evaluation	<ul style="list-style-type: none"> <li>• appearance</li> </ul>	Patient     Caregiver
<b>Mental/Cognitive State</b>		Structured exam. if used:
Arousal/ Alertness/ Attention/ Concentration	<ul style="list-style-type: none"> <li>• confusion/clarity</li> <li>• excitement/reactivity</li> <li>• state of consciousness</li> </ul>	Subject     Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 2 of 5

Area	Probes	Notes
Orientation	<ul style="list-style-type: none"> <li>• time</li> <li>• place</li> <li>• person</li> <li>• time relationships</li> <li>• travel</li> <li>• find his/her way</li> <li>• recognises self/others/objects</li> <li>• reacts appropriately</li> </ul>	Patient
		Caregiver
Memory	<ul style="list-style-type: none"> <li>• registration</li> <li>• recall</li> <li>• long term/remote</li> <li>• recall for past events</li> </ul>	Patient
		Caregiver
Language/Speech	<ul style="list-style-type: none"> <li>• fluency/ expressive language</li> <li>receptive language</li> <li>• comprehension</li> <li>• paraphasia/word finding</li> <li>• naming, amount</li> <li>• repetition</li> <li>• follows directions</li> </ul>	Patient
		Caregiver
Praxis	<ul style="list-style-type: none"> <li>• constructional ability</li> <li>• ideational praxis</li> <li>• ideomotor/imitation</li> </ul>	Patient
		Caregiver
Judgment/ Problem solving/ Insight	<ul style="list-style-type: none"> <li>• patient's behavior in situations requiring judgment</li> </ul>	Patient
		Caregiver



**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 3 of 5

Area	Probes	Notes
<b>Behavior</b>		
Thought content	<ul style="list-style-type: none"> <li>• organization</li> <li>• appropriateness</li> <li>• hostile expression</li> </ul>	Patient
		Caregiver
Hallucinations/ Delusions/ Illusions	<ul style="list-style-type: none"> <li>• auditory/visual</li> <li>• misperceptions</li> <li>• systematized/developed</li> </ul>	Patient
		Caregiver
Behavior/Mood	<ul style="list-style-type: none"> <li>• affect/lability</li> <li>• unusual/bizarre</li> <li>• uninhibited/sexually inappropriate</li> <li>• motivation/energy</li> <li>• wandering/getting lost</li> <li>• agitation/aggression</li> <li>• hostility</li> <li>• depression-related</li> <li>• anxiety-related</li> <li>• appropriateness</li> <li>• cooperativeness</li> <li>• demanding/dependent</li> </ul>	Patient
		Caregiver
Sleep/Appetite	<ul style="list-style-type: none"> <li>• sleep disorder</li> <li>• insomnia (type?)</li> <li>• nocturnal activity</li> <li>• hyper-, hyposomnia</li> <li>• appetite/weight change</li> </ul>	Patient
		Caregiver
Neurological/ Psychomotor activity	<ul style="list-style-type: none"> <li>• overall motor activity</li> <li>• posture/gait</li> <li>• movement disorder</li> <li>• unusual motor behavior</li> <li>• daily patterns</li> <li>• pacing</li> </ul>	Patient
		Caregiver

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

Caregiver & Patient Examination - ADCS - CGIC Page 4 of 5

Area	Probes	Notes
<b>Functioning</b>		
Basic and complex (instrumental) functional ability	• mobility	Patient
	• hygiene/grooming	
	• dressing	Caregiver
	• self-feeding	
	• shopping	
	• household chores/hobbies	
	• finances	
• driving		
Social function	• participation in: social interactions community activities	Patient
		Caregiver
	• independence	
	• helplessness	

**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change (CGIC)**

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Notes, comments, summary statement:

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Information from other sources:



**NRX-US4: Effect of NeuroAD, Combined TMS Stimulation and Cognitive Training, on the cognitive function of Mild to Moderate Alzheimer Patients**

**Clinical Global Impression of Change Rating**

**Week 12 visit**

**Subject ID and Initials:** \_\_\_\_\_  
**Examiner** \_\_\_\_\_ **Examination Date**   -   -    
Month Day Year

**Clinical Impression of Change from Baseline:**

- Marked improvement
- Moderate improvement
- Minimal improvement
- No change
- Minimal worsening
- Moderate worsening
- Marked worsening

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
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