Universitätsspital Basel | University of Basel | RC2NB Research Center for Clinical Neuroimmunology and Neuroscience Basel | Neurostatus-UHB

neuroStatus SMARTCARE

Neurostatus-SMARTCARE in comparison to standard Neurostatus-EDSS®
- a prospective Swiss multicenter randomized cross-over study-

Giulia Mallucci[1], Andrea Zimmer[1], Nikolaos Sfikas[2], Alex Ocampo2, Ioanna Athanasopoulou[1], Christian Kamm[3], Katrin Parmar[4], Bernd Kieseier[2], Amit Khanna[2], Ludwig Kappos[1], Marcus D'Souza[1,3]

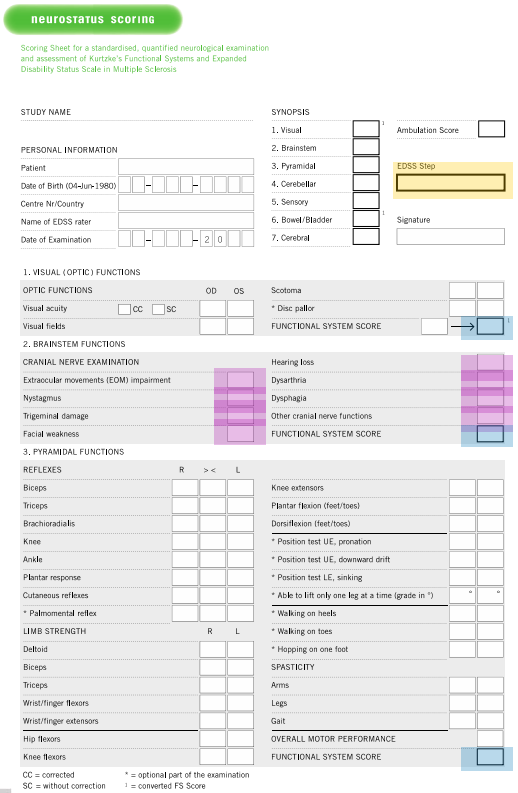
[1]Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB), Departments of Head, Spine and Neuromedicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, Basel, Switzerland; [2]Novartis Pharma AG, Basel, Switzerland [3]MS-Zentrum und neuroimmunologische Sprechstunde, Neurozentrum, Luzerner, Kantonsspital, Luzern, Switzerland; [4]Reha Rheinfelden, Rheinfelden, Switzerland; [5]Neurologic Clinic and Policlinic, Department of Head, Spine and Neuromedicine, University Hospital of Basel, Basel, Switzerland

Background

- The **barriers** to accessing Multiple Sclerosis (MS) healthcare are wide-ranging and complex and affect both clinical practice and clinical trials settings
- COVID-19 pandemic exacerbated limitations and acted as booster of changes and innovations
- Neurostatus-eEDSS is the standard assessment deployed in MS randomized clinical trials, typically serving as the primary endpoint.
- **Neurostatus-SMARTCARE** aims to reduce and smooth some of the disparities in accessing MS healthcare (clinical trial setting) by increasing the number of Non-Neurologist Health Care Professionals (HCPs) licensed to perform the Neurostatus-(e)EDSS
- Neurostatus-SMARTCARE is developed to be used in Home-setting

neuroStatus SMARTCARE

Objectives



neurostatus scoring

Scoring Sheet for a standardised, quantified neurological examination and assessment of Kurtzke's Functional Systems and Expanded Disability Status Scale in Multiple Sclerosis

STUDY NAME

PERSONAL INFORMATION

Patient

Date of Birth (04-Jun-1980)

Centre Nr/Country

Name of EDSS rater

Date of Examination

SYNOPSIS

1. Visual
2. Brainstem
3. Pyramidal
4. Cerebellar
5. Sensory
6. Bowel/Bladder
7. Cerebral

Ambulation Score

EDSS Step

Signature

1. VISUAL (OPTIC) FUNCTIONS

OPTIC FUNCTIONS — OD OS

Visual acuity — CC SC

Visual fields

Scotoma

* Disc pallor

FUNCTIONAL SYSTEM SCORE

2. BRAINSTEM FUNCTIONS

CRANIAL NERVE EXAMINATION

Extraocular movements (EOM) impairment

Nystagmus

Trigeminal damage

Facial weakness

Hearing loss

Dysarthria

Dysphagia

Other cranial nerve functions

FUNCTIONAL SYSTEM SCORE

3. PYRAMIDAL FUNCTIONS

REFLEXES — R >< L

Biceps

Triceps

Brachioradialis

Knee

Ankle

Plantar response

Cutaneous reflexes

* Palmomental reflex

LIMB STRENGTH — R L

Deltoid

Biceps

Triceps

Wrist/finger flexors

Wrist/finger extensors

Hip flexors

Knee flexors

Knee extensors

Plantar flexion (feet/toes)

Dorsiflexion (feet/toes)

* Position test UE, pronation

* Position test UE, downward drift

* Position test LE, sinking

* Able to lift only one leg at a time (grade in °)

* Walking on heels

* Walking on toes

* Hopping on one foot

SPASTICITY

Arms

Legs

Gait

OVERALL MOTOR PERFORMANCE

FUNCTIONAL SYSTEM SCORE

CC = corrected
SC = without correction

* = optional part of the examination
¹ = converted FS Score

FIRST Objective

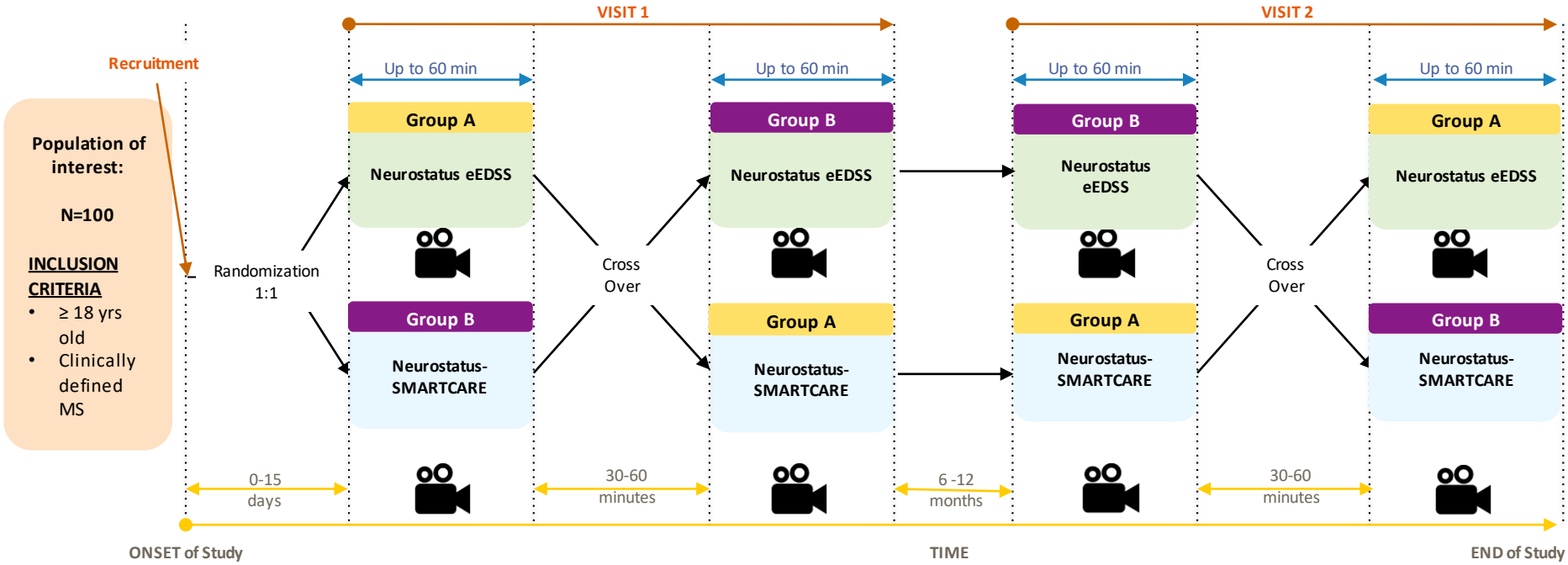
EDSS step concordance rate between the neurologist and HCP

Secondary Objective

- **Subscores** concordance rate between the neurologist and HCP
- **FSs** concordance rate between the neurologist and HCP
- To test if a recorded video of the assessment enables independent EDSS experts to determine the reasons of discordance
- To detect errors typical for an individual rater to offer targeted re-training
- To determine concordance with regard to capturing adequately changes in EDSS step

neuroStatus SMARTCARE

Study Design



Both groups at both times are videorecorded

Swiss multicenter study: University Hospital Basel; Kantonspital Luzern; Reha Rheinfelden

neuroStatus SMARTCARE