Thank you for joining the monthly EAP webinar!

We are admitting audience members from the waiting room.

Please allow a few moments for the webinar to begin.

SEA-NOBI-ALS

SCALABLE EXPANDED ACCESS WITH ANALYSIS OF NEUROFILAMENT AND OTHER BIOMARKERS FOR IBUDILAST IN ALS

NINDS grant 1U01NS136022-01A1

NEALS 2025

Björn Oskarsson, MD, FAAN
Mayo Clinic Florida

Expanded Access in ALS

- 2021 ACT for ALS
- 5th project, the only 2024 grant
- Alongside an ongoing clinical trial
- Shorter and smaller than 1st proposal

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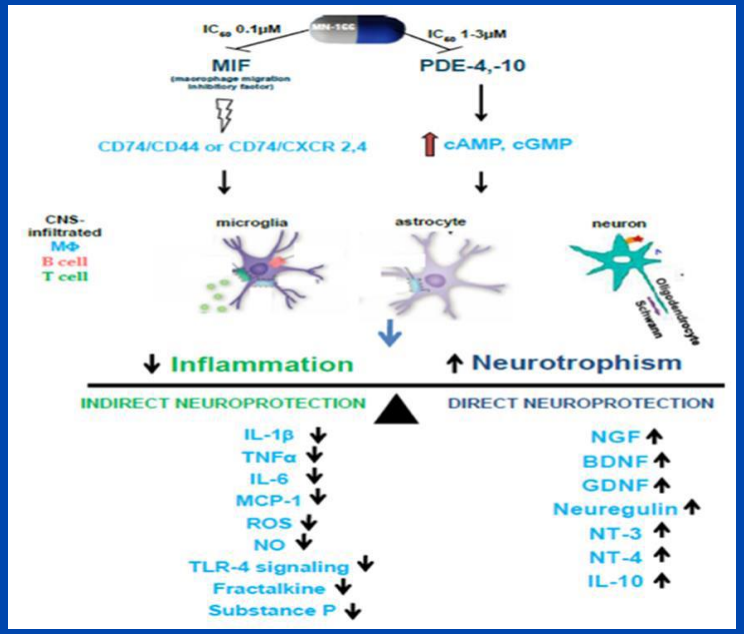
Ibudilast MN-166



- orally available small molecule
- penetrates the CNS well
- Inhibits pro inflammatory cytokine macrophage migration inhibitory factor (MIF) and PDE 3, 4, 10
- Demonstrated neuroprotective action and glial cell attenuation
- 1989 Approved in Japan
- Excellent safety

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Phase 1B/2A projects

- NCT 02238626 - B. Brooks
- Single-center, randomized double blind (6 months), placebo-controlled trial followed by OLE (6 months).
- This study showed no overall change in disease progression between placebo and MN-166
- More patients receiving MN-166 remained stable or improved ALSFRS-R, ALSAQ-5 and average muscle strength in the post-hoc analysis.

Responder Analysis in MN-166-ALS-1201			
Parameter	Responder category	Placebo (n=16)	MN-166 (n=33)
ALSFRS-R Total score	Stable or improved	2/16 (12.5%)	7/33 (21.2%)
ALSAQ-5		4/16 (25%)	17/33 (51.5%)
MMT		4/16 (25%)	11/33 (33.3%)

- NCT02714036 - S. Babu/ N. Attasi
- Phase 1b, open-label, safety, pharmacodynamic, and biomarker study
- [11C]-PBR28 uptake PET
- N=35 up to 36 week
- No change PBR28-PET
- N=10 No change in serum neurofilament light (NfL)

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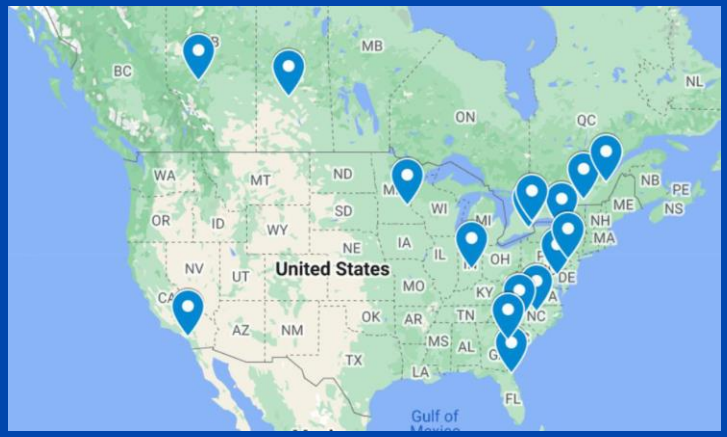
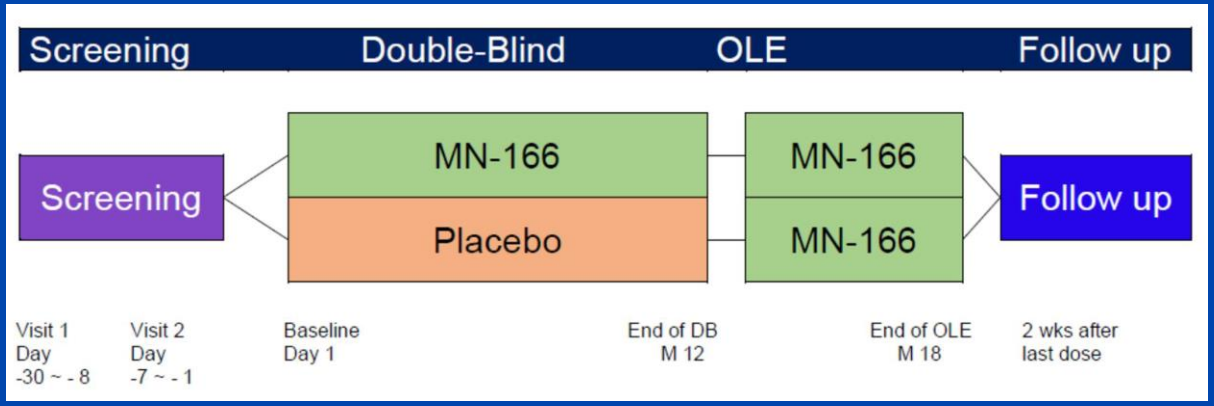
COMBAT-ALS (NCT04057898)

- Phase 2b/3 Trial of MN-166 (Ibudilast) in ALS
- N=230 (230 enrolled,197 randomized)



Bedlack R, Bodkins C, Dionne A, Elliott M, Genge A, Gosselin S, Goyal N, Johnston W, Maiser S, Maragakis N, Meyer JA , Rivner M, Schellenberg K, Turnbull J, Walsh A, Zinman L, Oskarsson B



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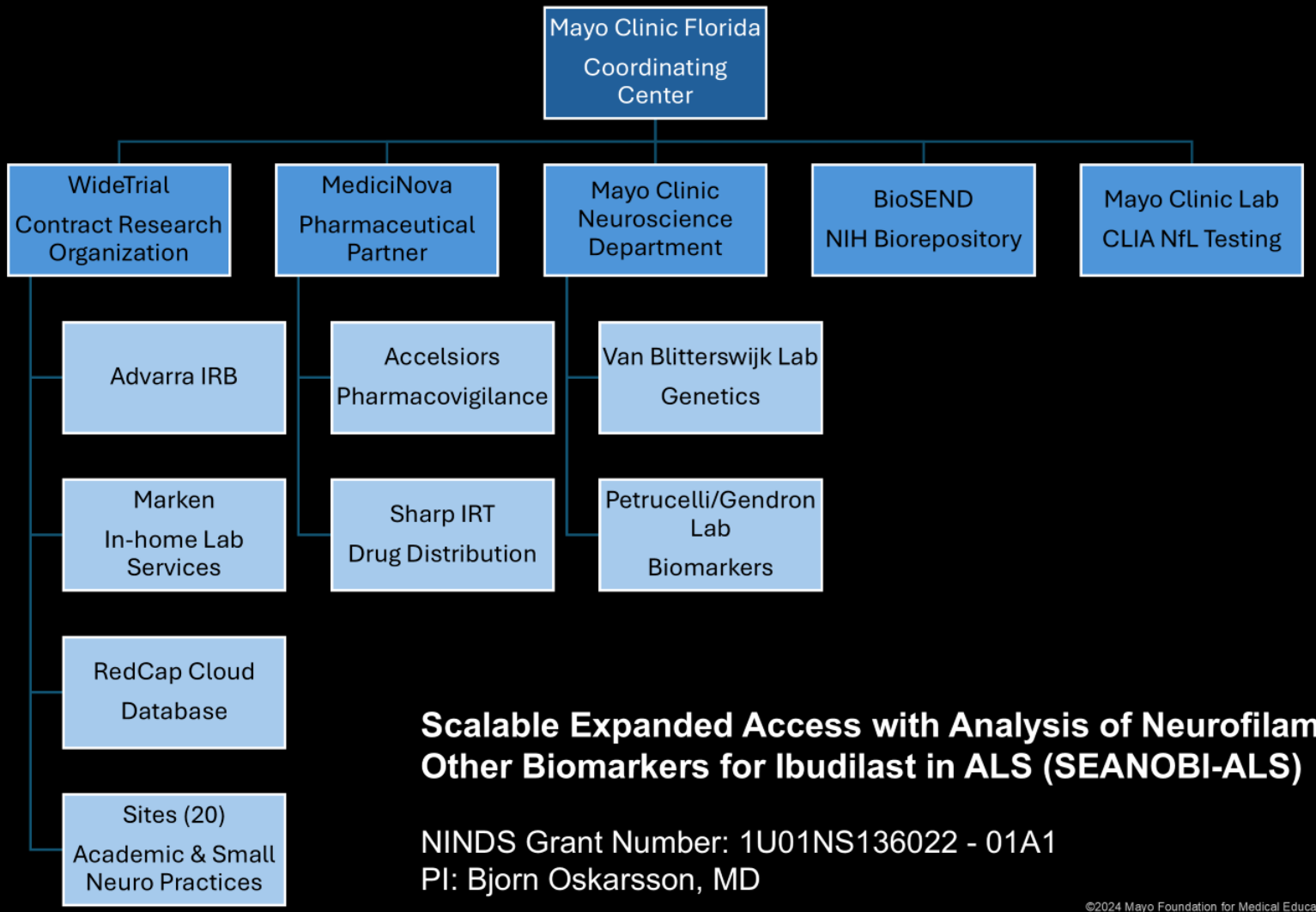
Atlantic Beach, Florida

Provisional Organization chart



Scalable Expanded Access with Analysis of Neurofilament and Other Biomarkers for Ibudilast in ALS (SEANOBI-ALS)

NINDS Grant Number: 1U01NS136022 - 01A1
PI: Bjorn Oskarsson, MD

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SEANOBI

- 200 patients
- 15 sites are selected
  - 3 Mayo clinic + US COMBAT + 3 other (UCSF satellites, NSEU, Semmes Murphey)
- 1st patient in spring 2025
- No patients who can participate in trials
- Otherwise broad inclusion criteria
- Neurofilament light - results to patient and treating physicians
- User (physician) friendly interface

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Neurofilament light and other outcomes

- levels are elevated in ALS
- levels are stable over time
- a person can serve as their own control
- CLIA certified results will be provided to patients and their physicians
- ALSFRSr, ALSAQ5 and NeuroQOL
- DNA long read sequencing
- inflammatory bio markers

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  - DSMB Americo Fernandes, MD, U Nebraska
  - DSMB Robert Silbergleit, MD U Michigan
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  - Rosa Rademakers, PhD
  - Tania Gendron, PhD
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  - MDA

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Treatment