

HEALEY ALS Platform Trial

Weekly Q&A – Jan 26, 2023



Healey Center

Sean M. Healey & AMG Center
for ALS at Mass General



Calico



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MASTER PROTOCOL

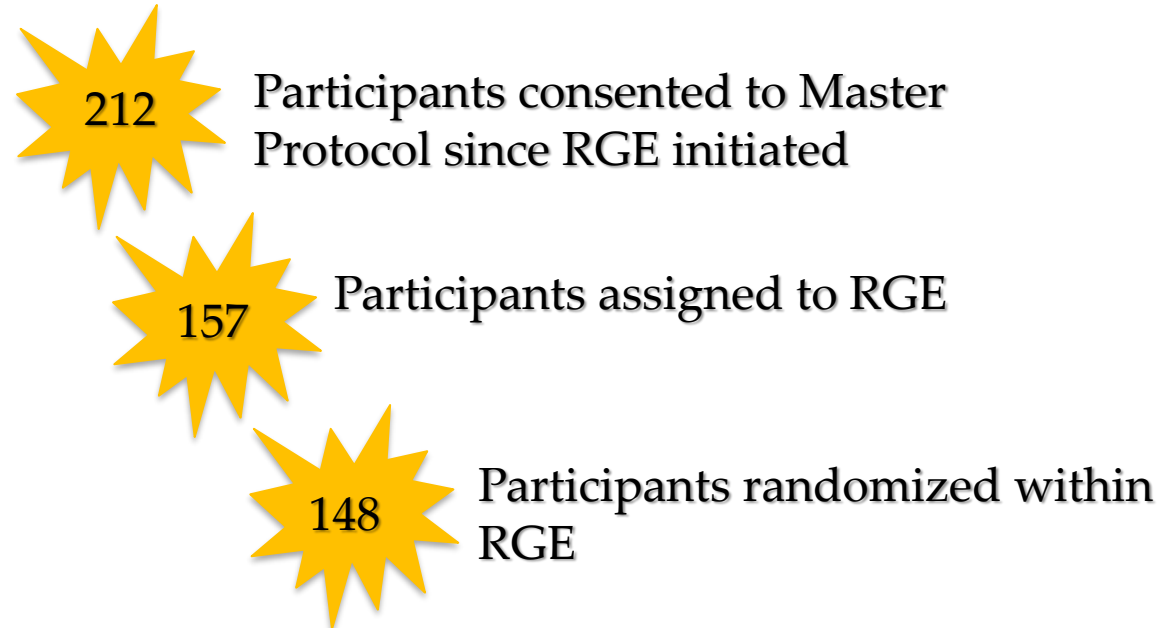
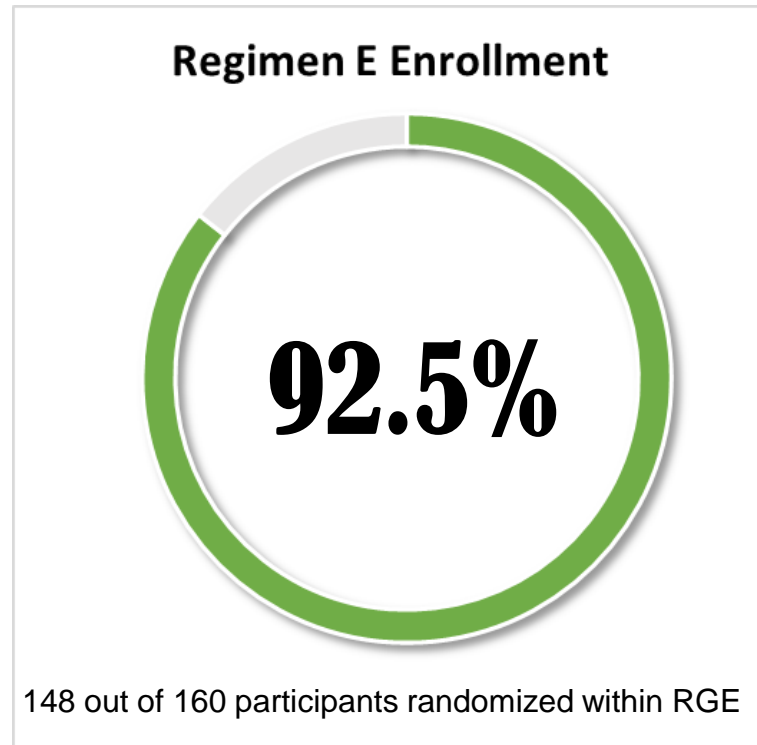
- Regimen A
- Regimen B
- Regimen C
- Regimen D
- Regimen E
- Regimen F
- Regimen G



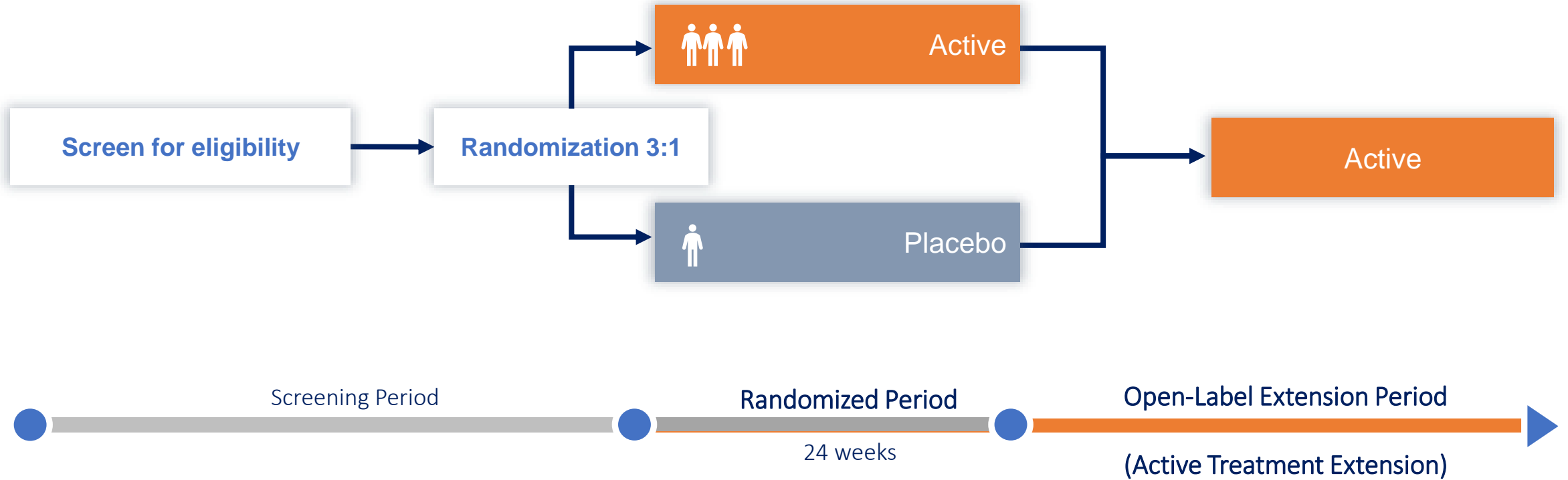
ENROLLING

IN START-UP

Regimen E Updates (as of Jan 26, 2023)



Schema for Each Regimen



Regimen C Update –

- October 2022: **Regimen C** top line results announced

While the primary endpoint was not met, exploratory analyses of the secondary survival endpoint demonstrated a significant reduction in risk of death or permanently assisted ventilation when adjusting for baseline risk imbalances in the CNM-Au8 regimen for the 30 mg dose

- Based on Phase 2 study results, Clene is preparing for a Phase 3 Trial of CNM-Au8
- Early 2023: **Regimen C** Open Label Extension is closing
- CNM-Au8 Expanded Access Protocol (EAP) is launching

- Open Label Extension (OLE) to transition to Clene Expanded Access Program (EAP)
 - Participants in OLE for Regimen C will be prioritized for the Clene EAP
 - During transition from OLE to EAP, participants in Regimen C will have option to transfer to a different Platform Trial site
 - EAP broadens access to CNM-Au8, so it will be available to more people (including those who were not eligible to participate in Platform Trial Regimen C)
 - EAP details, eligibility criteria, site locations, and contact info will be posted on ClinicalTrials.gov

CNM-Au8 Q&A



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Regimen Co-Lead (Regimen C)
Massachusetts General Hospital



Michael Hotchkin

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