Botox Case Study

Phase 1

A Phase I, Randomised, Double-blind, Parallel-group, Single-centre, Comparative Study to Evaluate the Pharmacodynamic Profile of Dysport, Botox and Xeomin in the Extensor Digitorum Brevis Model in Healthy Adult Male Participants.

Services
Clinical Services, Labs, ICF development

1 Clinical Site
Manchester, UK

Healthy Volunteers
Male Adults

KEY STUDY DELIVERABLES

PARTICIPANT RECRUITMENT & RETENTION

45
RECRUITMENT TARGET

45
PARTICIPANTS ENROLLED

100%
RECRUITED TO TARGET

Enrolment target of 45 participants met within 2 months

STUDY TIMELINE (NO OF MONTHS)

MAC completed the study within 11 months

OBJECTIVES, ENDPOINTS AND ESTIMANDS

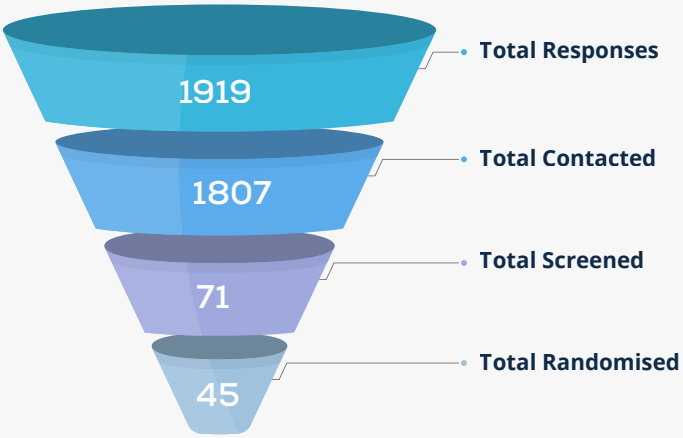
Primary estimand and clinical question of interest

"What is the average difference between Dysport 40 U and the active comparators Botox 16 U and Xeomin 16 U in EDB CMAP total amplitude inhibition at Week 28 in healthy adult male participants".

A key intercurrent event for all estimands is study discontinuation for any reason before timepoint of assessment.

Objectives	Endpoints
Primary	
To demonstrate longer duration of action of Dysport compared with Botox and Xeomin in EDB CMAP when applying a dose ratio based on approved FDA total recommended doses	• CMAP total amplitude at Week 28, measured as relative change from Baseline (%) • Key intercurrent event: ◦ Study discontinuation for any reason before timepoint of assessment
Secondary	
To compare the duration of pharmacodynamic action of a single BoNT-A administration on EBD CMAP	• CMAP total amplitude at Week 40, measured as relative change from Baseline (%) • Incidence at Week 28 of recovery of CMAP total amplitude, defined as total amplitude return to at least 85% of the Baseline value • Incidence of recovery of CMAP total amplitude at Week 40
To further characterise the pharmacodynamic profile of a single intramuscular administration of study intervention at reducing the CMAP total amplitude of the stimulated EDB	• Time to onset of action defined as first timepoint where EDB CMAP total amplitude is 85% or lower than the Baseline value • Duration of response defined as time period between time to onset and time to recovery • Maximal inhibition (maximal effect) reached • Time to maximal effect on the CMAP total amplitude of stimulated EDB
To assess safety	• Type, incidence and severity of TEAEs, SAEs, AEs, (or SAEs) leading to withdrawals • AESIs

PARTICIPANT FUNNEL & DEMOGRAPHIC



AVERAGE DISTANCE TRAVELLED

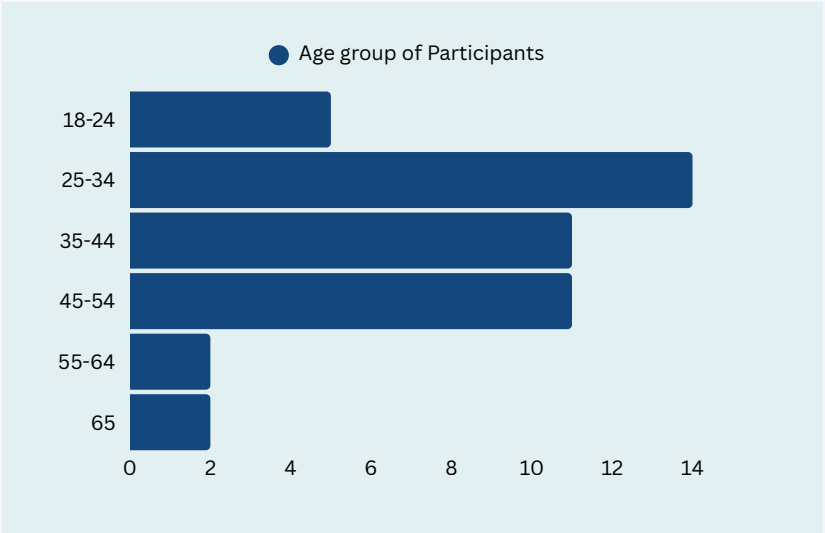
SCREENED	RANDOMISED
21.8	18.7
MILES	MILES

HEALTHY VOLUNTEERS

MALE SUBJECTS

18-65

AGE



MAC **expedited the study timelin**e, with recruitment completed in just **two months**. All participants completed the study, with no dropouts.