Background: Individuals elect to have aesthetic treatment with Botulinum toxin to enhance their appearance and reduce unwanted facial lines, primarily those associated with negative facial expressions such as frowning. Satisfaction with the outcomes of facial aesthetic treatments is dependent on a number of factors one of which is the duration of clinical benefit. Duration of benefit influences the frequency of retreatment and annual costs to the patient. Despite the importance of this factor, outcome measures reported for duration are often poorly defined in clinical trials.

Methods: This study was designed to determine the duration of clinical efficacy of onabotulinumtoxinA in glabellar lines from pivotal phase III clinical trial data. For inclusion in the analysis, trials required a standard dose and injection pattern (total dose of 20U administered to the glabellar muscles), and similar overall study design. Duration of clinical effect for pooled data was calculated using the Kaplan-Meier method. Responders at day 30 (defined as a score of none or mild from a previous score of moderate or severe) were included in the analysis which was based upon investigator-evaluated Facial Wrinkle Scale (FWS) scores at maximum frown .

Results: Four randomized double-blind placebo-controlled clinical trials were included in the analysis, encompassing 859 subjects with moderate or severe FWS from North America and Asia, of which 621 received onabotulinumtoxinA (20U) for the intent to treat population. 84.2% of treated subjects were identified as responders at day 30 post-injection. For these responders, the median duration of efficacy was 120 days, with 25^{th} and 75^{th} percentiles of 91 and 126 days, respectively.

Conclusions: Pooled results from 4 global phase III pivotal trials on onabotulinumtoxinA treatment of glabellar lines has demonstrated that in 523 subjects of diverse ethnic backgrounds, treatment with the optimal dose of 20U results in a sustained clinical benefit of 4 months.