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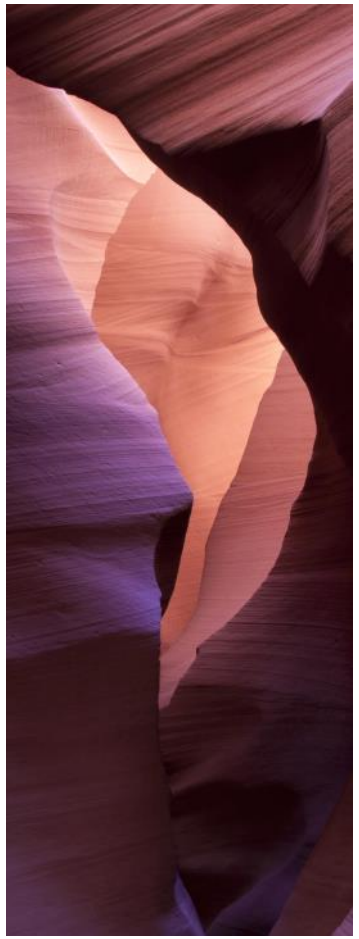

Late Breaking Abstract:

SAFETY AND EFFICACY OF DAXIBOTULINUMTOXINA FOR INJECTION (RT002) IN ISOLATED CERVICAL DYSTONIA: RESULTS OF A PHASE 2, DOSE ESCALATING STUDY

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Introduction

- Cervical dystonia (CD) is a chronic neurologic disorder characterized by involuntary patterned contractions of cervical musculature resulting in abnormal movements or postural changes of the head, neck, and shoulders.
- Currently available treatments for CD call for injection of botulinum toxin (BoNT) about every 3-4 months, or 3-4 times per year.
- DaxibotulinumtoxinA for Injection (RT002), a neuromodulator currently in clinical development, is comprised of a 150 kDa BoNT-A molecule and a proprietary peptide, with no animal-derived components or human serum albumin (HSA).
- Study Objectives:
  - To assess the safety and preliminary efficacy of RT002 for Injection in subjects with isolated CD
  - To evaluate the duration of effect of RT002 for Injection in the treatment of isolated CD

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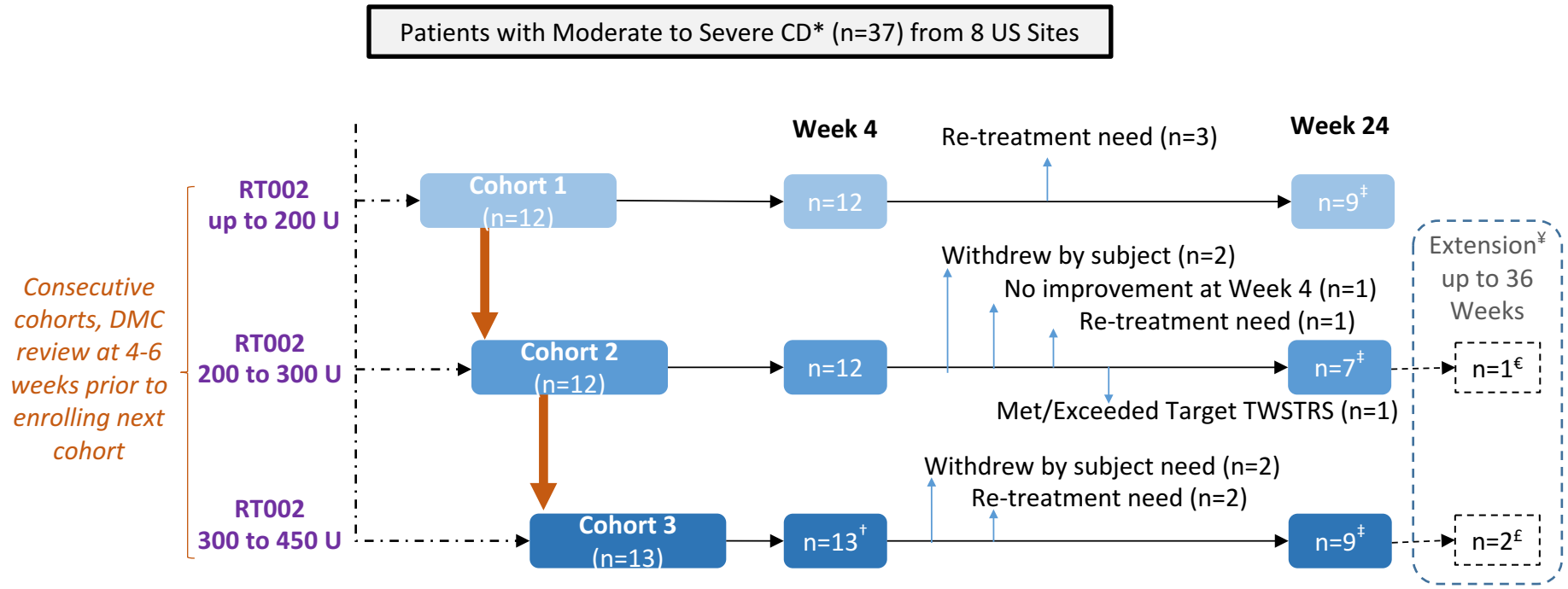
Dose-Escalating Study Design and Subject Disposition



Subjects were evaluated at 2-4 week intervals for 24-36 weeks or until loss of benefit.

*TWSTRS-Total ≥ 20, TWSTRS-Severity ≥ 15, and treatment-naïve or no BoNT within last 6 months.
†Two subjects missed the Week 4 visit. ‡Met/exceeded Target-TWSTRS at Week 24 for n=1 in Cohort 1 and n=2 in Cohort 2; at Week 20 for n=2 in Cohort 2; at Week 6 for n=1 in Cohort 3. ¥Added in the protocol as of January 2017.
€Completed Week 36. £Ongoing.

Demographics and Baseline Characteristics
By Cohort

	Cohort 1 (n=12)	Cohort 2 (n=12)	Cohort 3 (n=13)	All (n=37)
Mean age [range]	57 [46–74]	52 [32–70]	58 [30–69]	56 [30–74]
Females , n (%)	11 (92%)	8 (67%)	9 (69%)	28 (76%)
Caucasians, n (%)	12 (100%)	9 (75%)	11 (85%)	32 (86%)
Mean/Median CD duration (yrs) [range]	8.5/7.5 [0.4–21.7]	5.1/1.2 [0.0–24.1]	9.0/8.1 [0.6–23.3]	7.6/4.9 [0.0–24.1]
Prior treatment w/ BoNT	5 (42%)	4 (33%)	8 (62%)*	17 (46%)
Mean RT002 dose, U [range]	174 [100–200]	229 [200–300]	323 [300–450]	244 [100–450]
Mean TWSTRS Score:				
Total Score	43.8	44.9	43.7	44.1
Severity Score	20.1	21.4	21.8	21.1
Disability Score	12.8	12.3	11.5	12.2
Pain Score	11.0	11.2	10.4	10.8

*Three re-enrolled subjects received RT002 in Cohort 1 (n=2, 150 U and 200 U) and Cohort 2 (n=1, 200 U).

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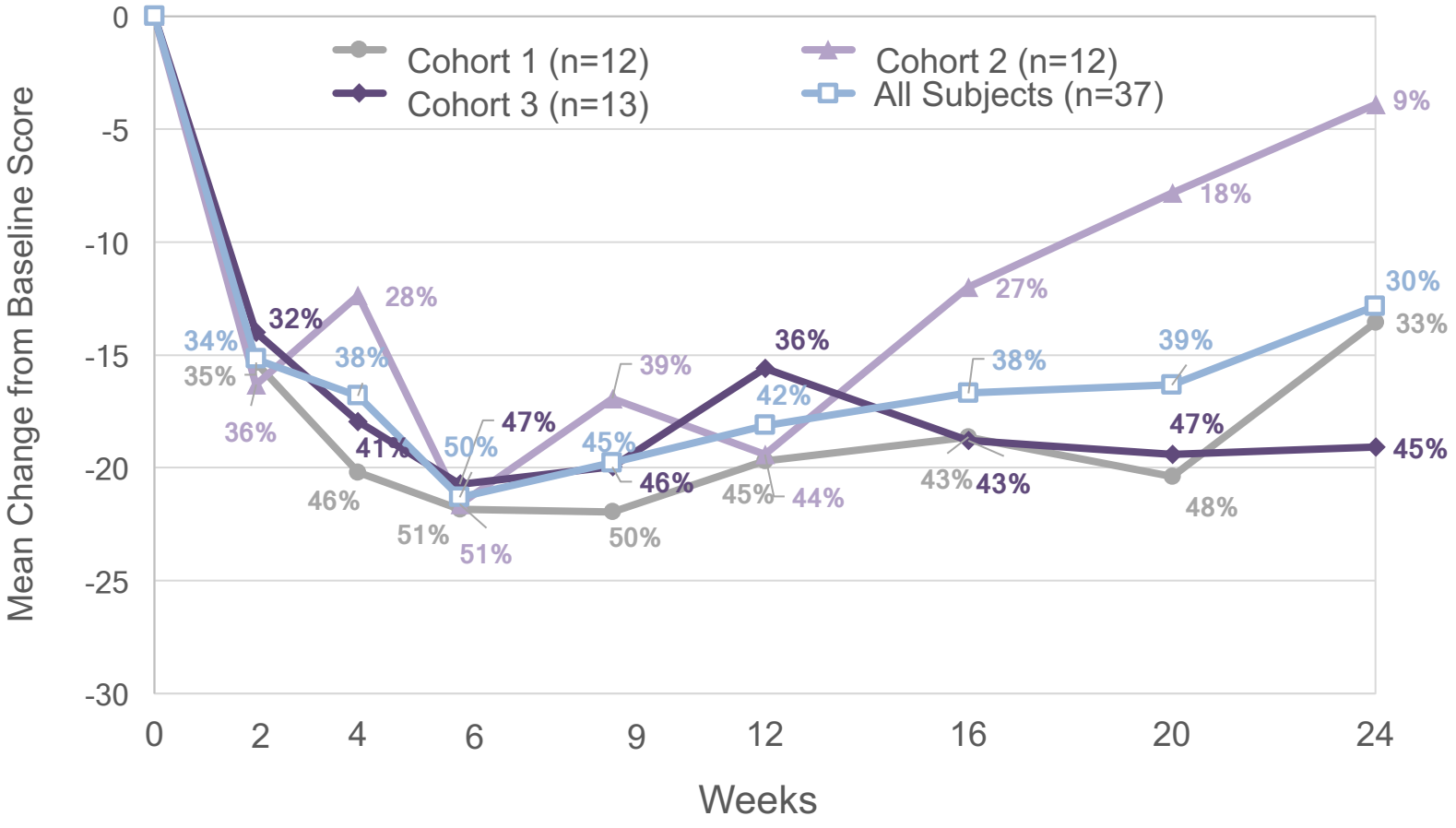
Reduction in TWSTRS-Total Scores Over Time
By Cohort

Clinically meaningful reduction in TWSTRS-Total Score beginning at Week 2 for all 3 Cohorts, with almost all of this benefit maintained through Week 24 for Cohorts 1 & 3



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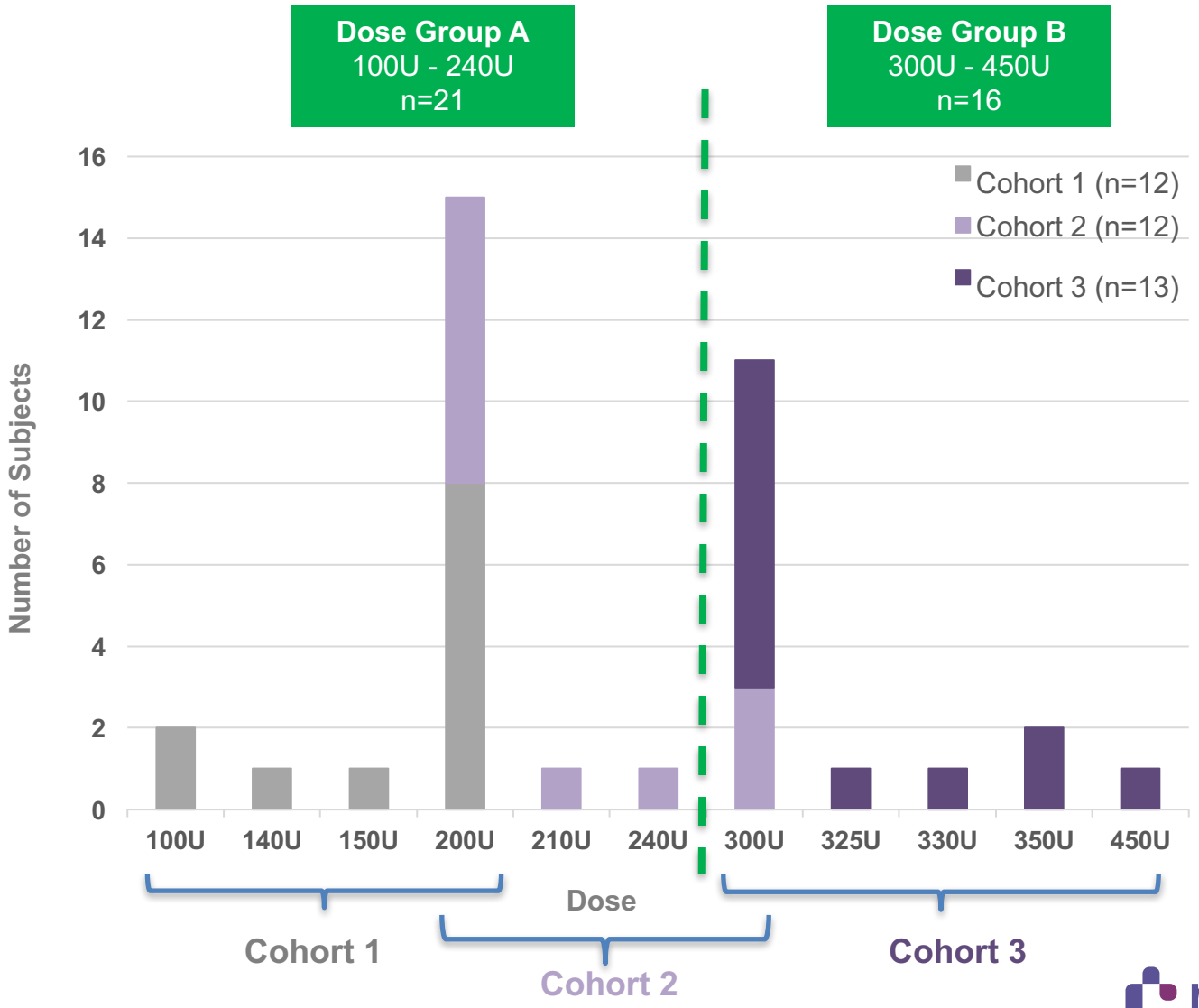
Subject Distribution by Dose



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Demographics and Baseline Characteristics
By Dose Group

	Group A 100-240 U (n=21)	Group B 300-450 U (n=16)	All (n=37)
Mean age [range]	54 [32–74]	58 [30–70)	56 [30–74]
Females, n (%)	18 (86%)	10 (63%)	28 (76%)
Caucasians, n (%)	18 (86%)	14 (88%)	32 (86%)
Mean/Median CD duration (yrs) [range]	7.3/4.8 [0.02–24.1]	7.9/7.2 [0.02–23.3]	7.6/4.9 [0.0–24.1]
Prior treatment with BoNT	9 (43%)	8 (50%)*	17 (46%)
Mean RT002 dose, U	188	319	244
Mean TWSTRS Score:			
Total Score	44.4	43.8	44.1
Severity Score	20.5	21.9	21.1
Disability Score	12.6	11.6	12.2
Pain Score	11.3	10.3	10.8

*Three subjects received RT002 in Cohort 1 or 2, and re-enrolled to Cohort 3.

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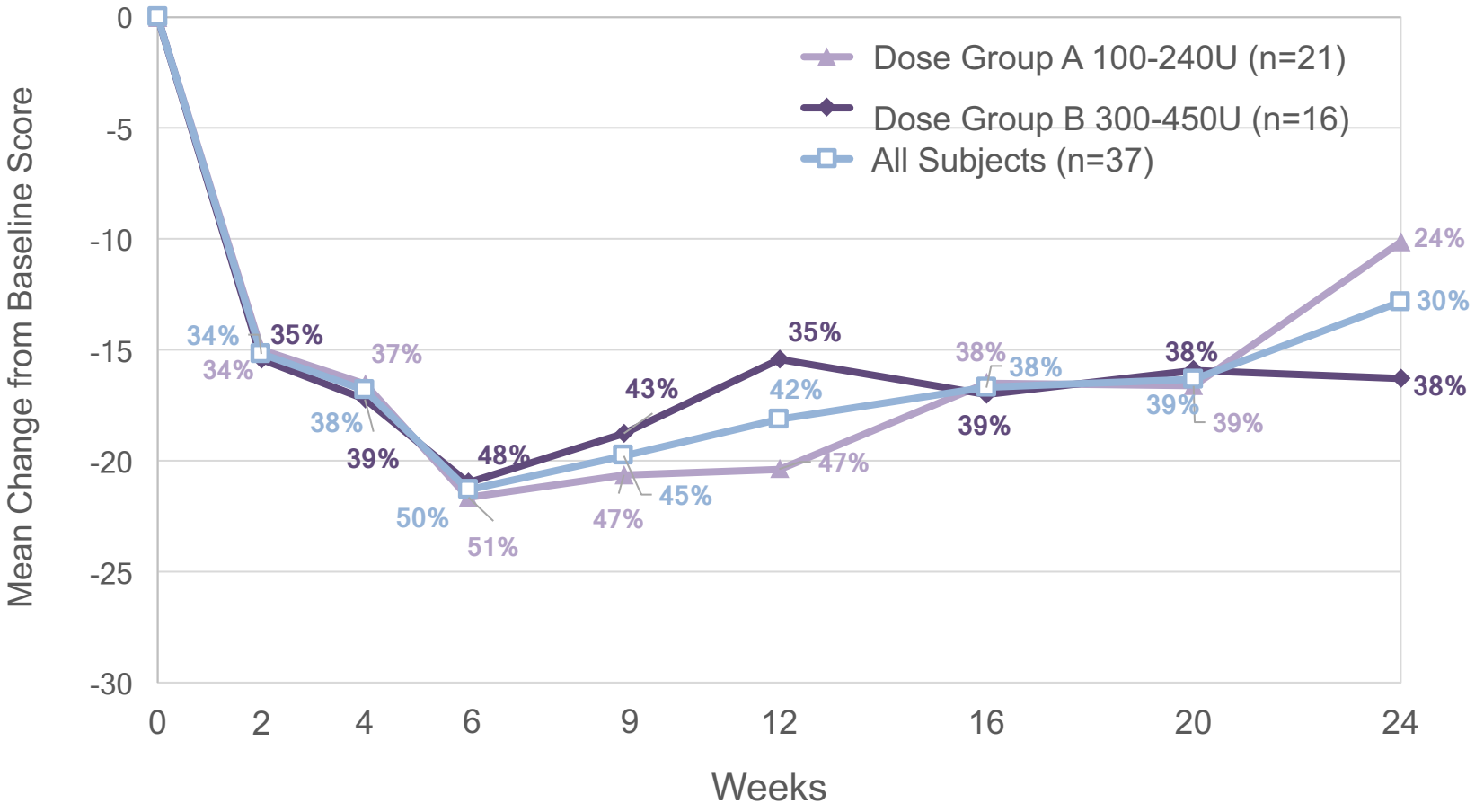
Reduction in TWSTRS-Total Score Over Time
By Dose Group

Clinically meaningful reduction in TWSTRS-Total Score of 34% for all subjects beginning at Week 2, with the majority of this benefit maintained through Week 24 in both dose groups



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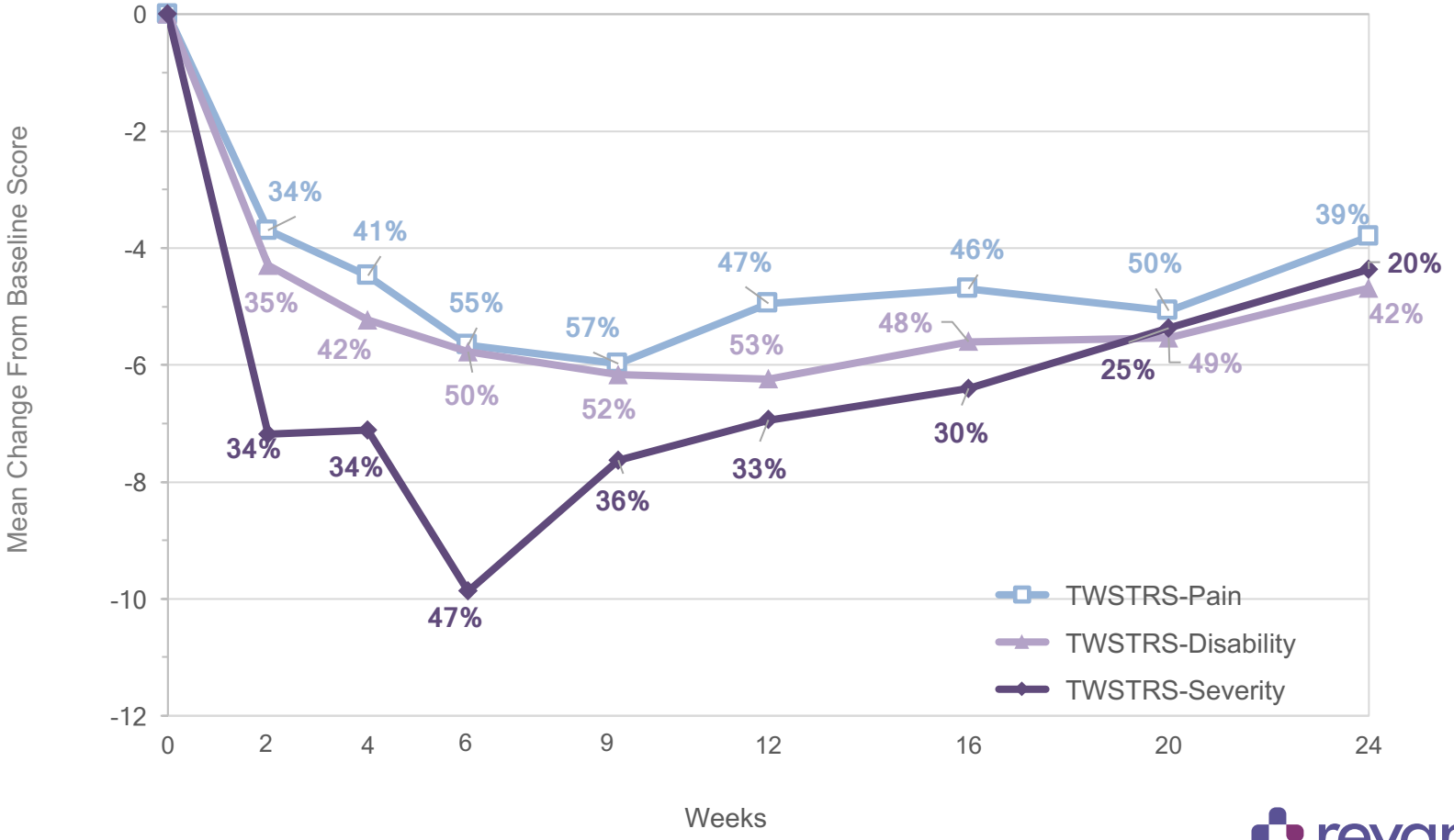
Reduction in TWSTRS Subscales Over Time

All Subjects, n=37

Clinically meaningful reduction in TWSTRS Severity (34%), Pain (41%), and Disability (42%) Subscale Scores observed at Week 4, with the majority of this benefit maintained through Week 24



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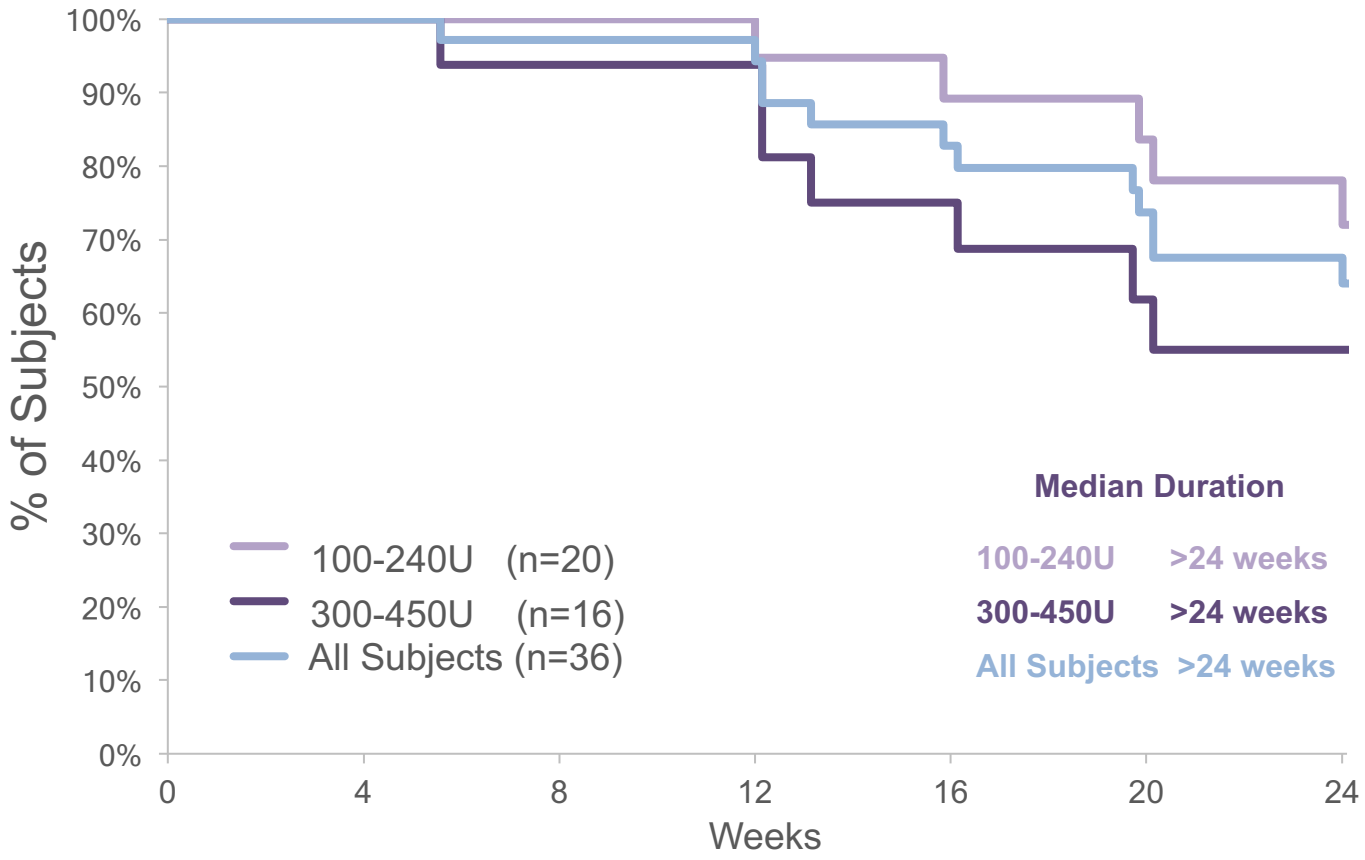
Duration of Effect

Defined by % Subjects Maintaining ≥ 20% of Treatment Benefit*

Median Duration of Response > 24 Weeks for Both Dose Groups



*Of subjects with Improvement at Week 4. Withdrawals due to need for retreatment are considered as events. Treatment benefit defined as the reduction in TWSTRS-Total score at Week 4.

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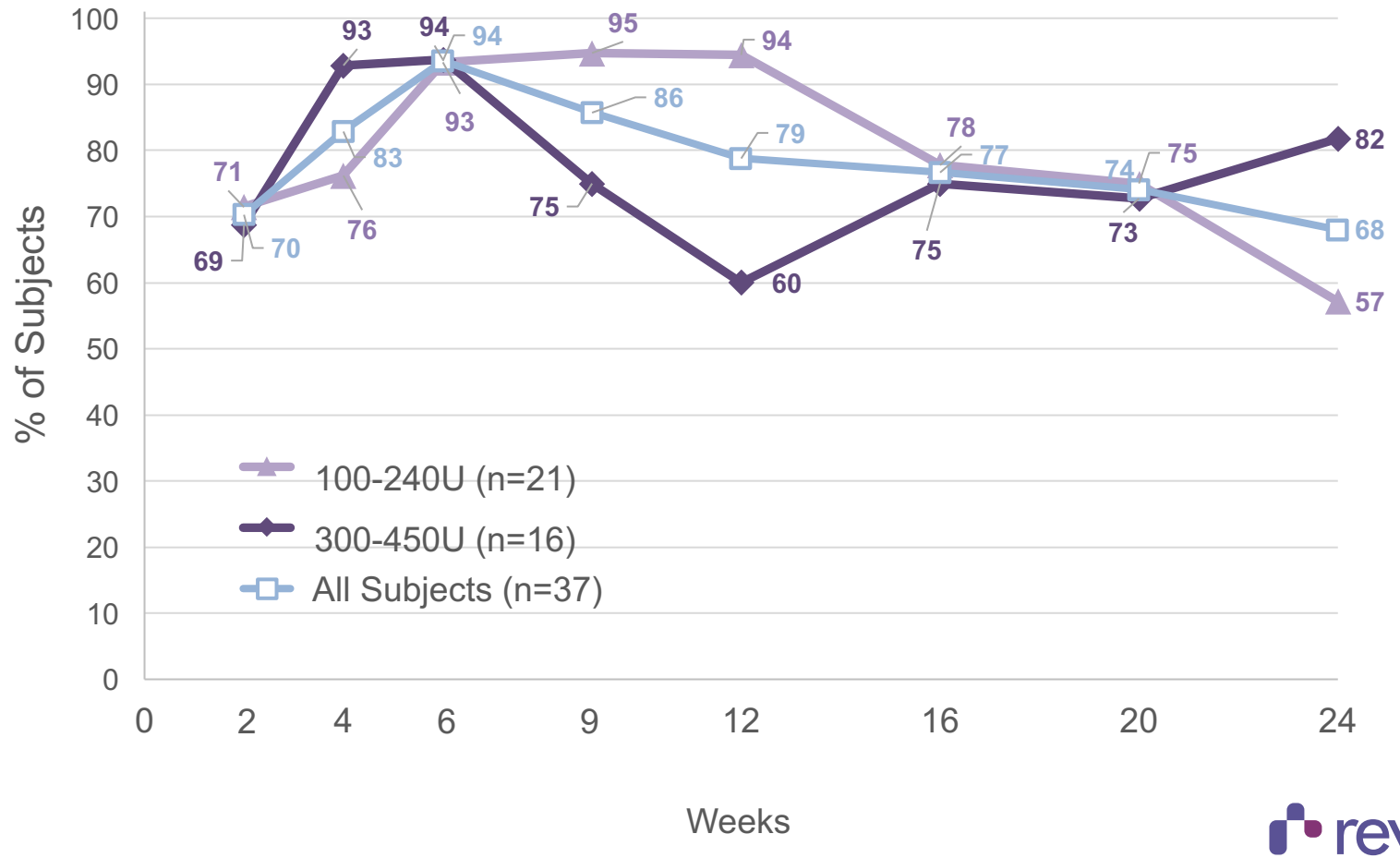
Response Rates by Dose Group

≥ 20% Reduction in TWSTRS-Total Score From Baseline

Greater than 2/3 of Subjects (68%) Experienced a Reduction of ≥ 20% from Baseline in TWSTRS-Total Score at Week 24



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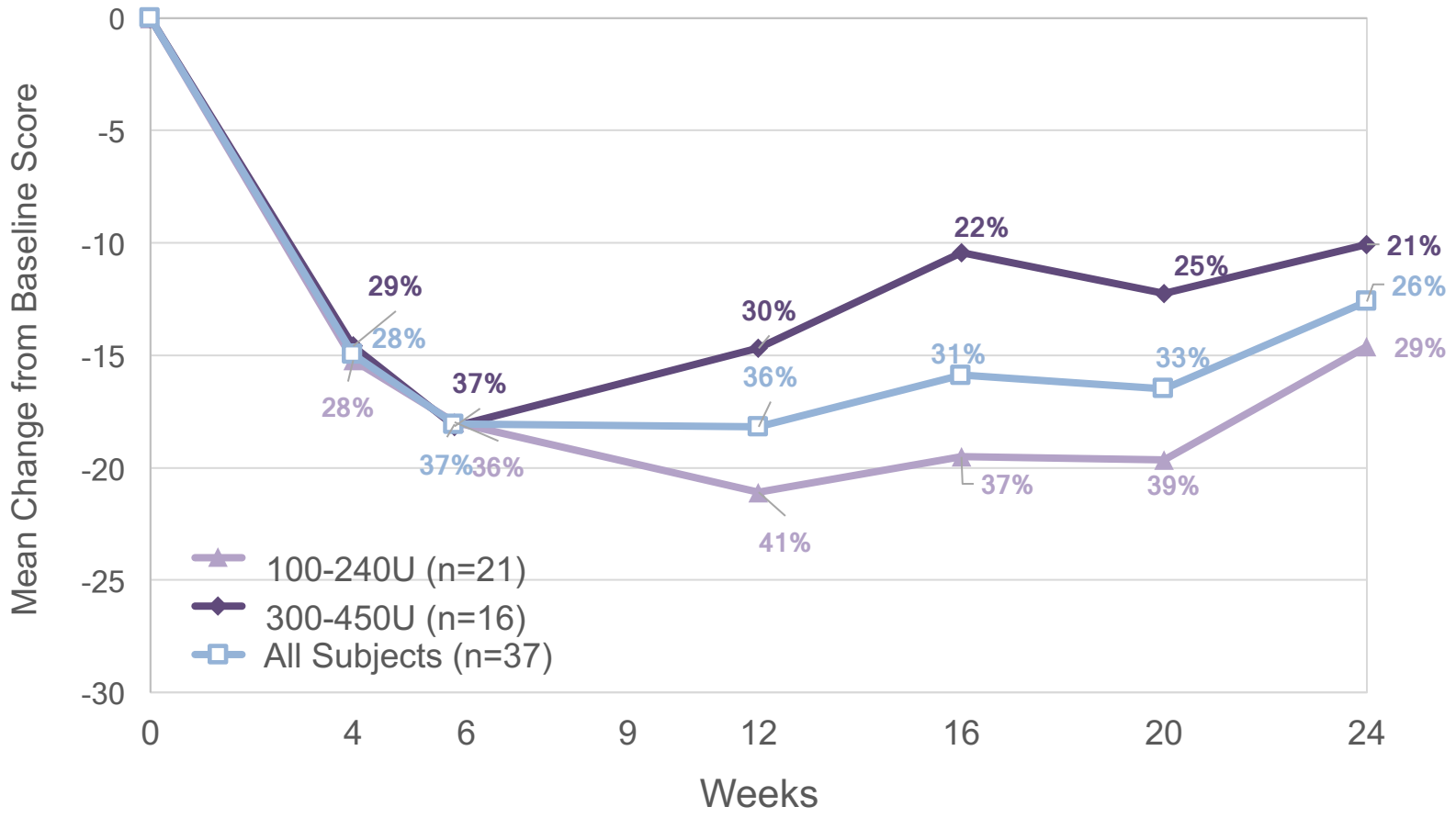
Quality of Life: Reduction in CDIP-58* Score Over Time
By Dose Group

Clinically meaningful reduction of 37% in CDIP-58 Score observed at Week 6 for all subjects, with the majority of this benefit maintained through Week 24



* Cervical Dystonia Impact Profile-58 Quality of Life Measure

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Efficacy Summary

- **Duration of Effect of > 24 Weeks:** Median duration of effect, defined as subjects maintaining ≥ 20% of the Week 4 treatment benefit (Target TWSTRS Score), was > 24 Weeks for both dose groups (Group A: 100-240U and Group B: 300-450U).

- **Improvement in Cervical Dystonia Signs and Symptoms:** A clinically significant mean reduction from baseline in the TWSTRS-Total Score of 16.8 (or 38%) was observed at Week 4 across all subjects.

  - Therapeutic benefit peaked at Week 6 with 50% mean reduction from baseline, and was maintained at ≥ 30% through Week 24.
  - Clinically meaningful reductions in TWSTRS-Severity, -Disability and -Pain Subscales were consistent and also observed at all time points.
  - 68% of subjects experienced a reduction of ≥ 20% from baseline in TWSTRS-Total Score at Week 24.

- **Quality of Life:** Meaningful reduction in CDIP-58 score of 37% (mean reduction of 18.1) was observed at Week 6, the majority of which was maintained (26%, mean reduction of 12.6) through Week 24 across all subjects.

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Safety Summary

- RT002 appeared to be generally safe and well tolerated across all cohorts and dose groups through Week 24, with no increase in treatment-emergent adverse events (TEAEs) upon dose escalation. All except one TEAE were mild or moderate in severity and no serious AEs were reported.
- Total of 22 treatment-related AEs in 13 of 37 subjects (35%) were reported and all resolved.
  - Reported in ≥2 cases included: dysphagia (14%), injection site erythema (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%), and muscle weakness (5%).
- Treatment-related AEs of special interest had similar or lower incidence rates vs. prior BoNT-A studies.
  - Dysphagia: 14% (5/37; all mild); average duration 35 days.
  - Muscular weakness: 5% (2/37, 1 mild, 1 moderate), both local.
  - Neck pain: 3% (1/37; only severe TEAE reported), duration of 2 days.

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