Disclaimer: The following information is fictional and is only intended for the purposes of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

Parallel Study Design Example: *Figures and Tables*

(A 24-Week Placebo-Controlled Trial of Remuverol in Adults with Disc Herniation)

Figure 1: Enrollment, Randomization, and Retention of the Study Participants

Participants were recruited based on physician referral at 3 academic medical centers between February 2017 and January 2018. The first participant was enrolled on March 1, 2017, and the last participant was enrolled in December 2017. Of 205 enrolled participants, 200 met inclusion criteria and were randomized to treatment. Randomized participants received either Remuverol 15 mg orally by tablet twice daily or matching Placebo twice daily.

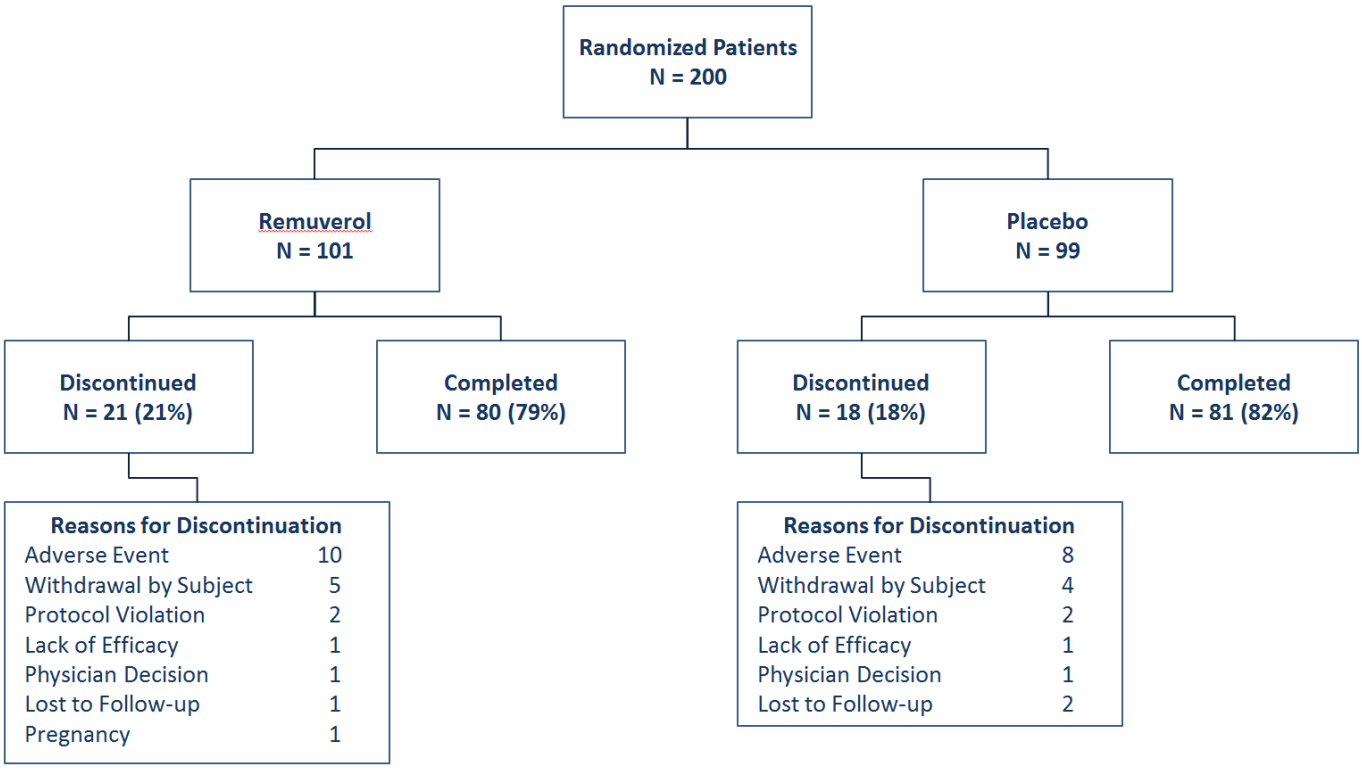

Table 1: Baseline Demographics and Disease Characteristics of Participants

Characteristic	Remuverol N = 101	Placebo N = 99	Total N = 200
Age, years, mean (SD)	34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex, n (%)			
Female	60 (59.4)	63 (63.6)	123 (61.5)
Race, n (%)			
African American	5 (4.95)	4 (4.04)	9 (4.50)
White	95 (94.06)	94 (94.95)	189 (94.50)
American Indian	1 (0.99)	1 (1.01)	2 (1.00)
Ethnicity, n (%)			
Hispanic	5 (4.95)	4 (4.04)	9 (4.50)
Region of Enrollment, n (%)			
United States	44 (43.56)	47 (47.48)	91 (45.50)
Canada	35 (34.65)	35 (35.35)	70 (35.00)
Mexico	22 (21.78)	17 (17.17)	39 (19.50)
QTF Classification of Spinal Disorder*			
Class 0, n (%) – *no pain*	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – *pain without radiation*	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – *pain with proximal extremity radiation*	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m2, mean (SD)	26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score, mean (SD)**	6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
Duration of Disc Herniation, years, mean (SD)	3.82 (3.18)	3.47 (2.95)	3.65 (3.07)
Height, cm, mean (SD)	186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight, kg, mean (SD)	77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

* Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from 0 (no pain) to Class 7 (spinal stenosis).

** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).

Table 2: Primary Outcome - Change from Baseline to Week 24 in SPS-11 24-Hour Pain Score

SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score – Baseline Score). Analysis was done on the Intent to Treat Population (all participants assigned to Remuverol or Placebo) with Last observation carried forward (LOCF) imputation method.

Measure	Remuverol		Placebo		Difference in Means (SD)*	P Value**
	N	Mean Change (SD)	N	Mean Change (SD)		
Change in SPS-11 Score	101	-3.84 ± 0.61	99	-2.08 ± 0.51	-1.76 (0.80)	0.002

*Treatment Difference = Remuverol – Placebo

** Mixed Models Analysis: it was calculated that 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α= 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.

Table 3: Secondary Outcomes - SPS-11 Pain Response Rates from Baseline to Endpoint

The response rate was defined as the number of participants with a reduction in SPS-11 pain score greater than or equal to the noted level (i.e., 50% or 75%) from baseline to endpoint. Analysis was based on the per-protocol population (all participants with baseline and week 12 or 24 pain scores available).

Time Frame	Remuverol		Placebo		P Value*
	N	No. Respondents	N	No. Respondents	
Response Rate at 50% Reduction in SPS-11 Pain					
Week 12	98	45	95	37	0.383
Week 24	76	73	81	67	0.009
Response Rate at 75% Reduction in SPS-11 Pain					
Week 24	76	57	81	43	0.005

* Fisher Exact

Table 4: All Serious Adverse Events and Non-Serious Adverse Events in >1% of Participants Receiving Remuverol or Placebo

All Adverse Events were collected by systematic assessment for up to 32 weeks using terms from the Medical Dictionary for Regulatory Activities (MedDRA), version 12.0. No participants died during the study.

EVENTS	REMUVEROL N = 101	PLACEBO N = 99
SERIOUS ADVERSE EVENTS	TOTAL AFFECTED = 4	TOTAL AFFECTED = 0
Anemia iron deficiency	1	0
Viral meningitis	1	0
Psoriasis	1	0
Idiopathic thrombocytopenic purpura	1	0
NON-SERIOUS ADVERSE EVENTS (>1%)	TOTAL AFFECTED = 98	TOTAL AFFECTED = 46
Earache	35	7
Hypothyroidism	27	25
Conjunctivitis	13	4
Nausea	12	7
Stomachache	10	2
Vomiting	10	3