CVT-301
Phase 3 Program Overview

Movement Disorder Society – Investor Event

June 5, 2017

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THIS PRESENTATION WILL DISCUSS CVT-301, AN INVESTIGATIONAL PRODUCT NOT APPROVED TO TREAT ANY DISEASE

This presentation is subject to risks and uncertainties that could cause actual results to differ materially, including: the ability to realize the benefits anticipated from the Biotie and Civitas transactions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg in the U.S., which will likely be materially adversely affected by the recently announced court decision in our litigation against filers of Abbreviated New Drug Applications (each, an "ANDA") to market generic versions of Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including INBRIJA™ (CVT-301, levodopa inhalation powder), or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market INBRIJA, any other products under development, or the products that we acquired with the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator Biogen in connection therewith; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

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Ron Cohen, M.D., CEO
Acorda Therapeutics

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Guest Speakers

MATTHEW STERN, M.D.

- Professor Emeritus of Neurology, Perelman School of Medicine (University of Pennsylvania)
- Former Director of the Parkinson's Disease and Movement Disorders Center
- Past President of the International Parkinson and Movement Disorder Society (MDS)
- Co-Founder of the Panorama Patient Network

PETER LeWITT, M.D.

- Professor of Neurology, Wayne State University School of Medicine
- Editor-in-chief of Clinical Neuropharmacology
- Founding member of the Parkinson Study Group
- Past Secretary of the International Parkinson and Movement Disorder Society (MDS)
- Principal investigator: CVT-301-004 study

DONALD GROSSET, M.D.

- Consultant Neurologist, Institute of Neurological Sciences, Queen Elizabeth University Hospital (Glasgow)
- Honorary Professor in Neurology, University of Glasgow
- Chair, Movement Disorder Advisory Group, Association of British Neurologists
- Principal investigator: CVT-301-005 study

Meeting Agenda

• Introduction	Ron Cohen, M.D., CEO
• OFF Periods in Parkinson’s Disease	Matt Stern, M.D.
• CVT-301: Rationale	Rick Batycky, Ph.D., CTO
• CVT-301: Overview of Phase 3 Program	Burkhard Blank, M.D., CMO
• CVT-301-004 Study Overview	Peter LeWitt, M.D.
• CVT-301-005 Study Overview	Donald Grosset, M.D.
• CVT-301 Summary / Closing	Burkhard Blank, M.D., CMO
• Q&A	

Matt Stern, M.D.
OFF Periods in Parkinson's Disease

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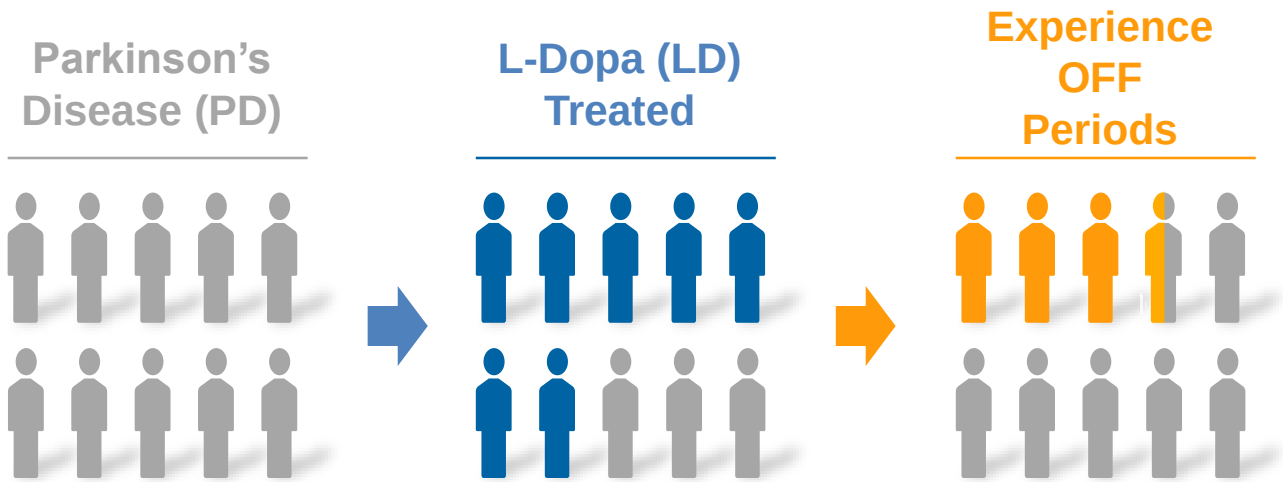
OFF Periods in PD: Epidemiology



	Parkinson's Disease (PD)	L-Dopa (LD) Treated	Experience OFF Periods
United States	~1M	~700K	350K+
Europe	~1.2M	~1.0M	~420K

Sources: Gustavsson A et al. European Neurology. 2011; 21:718-77, Parkinson's Disease. Decision Resources Group. January 2015 Parkinson's Disease Foundation; IMS National Prescription Audit

Prevalence and Incidence of PD in U.S.

Prevalence and Incidence	• **Affects approximately 1 million patients in the United States** – Prevalence in population >80 years old is 10% • **Approximately 60,000 new cases/year**
Onset	• **Average age of onset is 60 years**

Statistics on Parkinson's. Parkinson’s Disease Foundation. www.pdf.org/en/parkinson_statistics. Accessed May 2017
Olanow CW et al. Neurology. 2001;56(suppl 5):S1.

Impact of PD Progression and OFF Periods

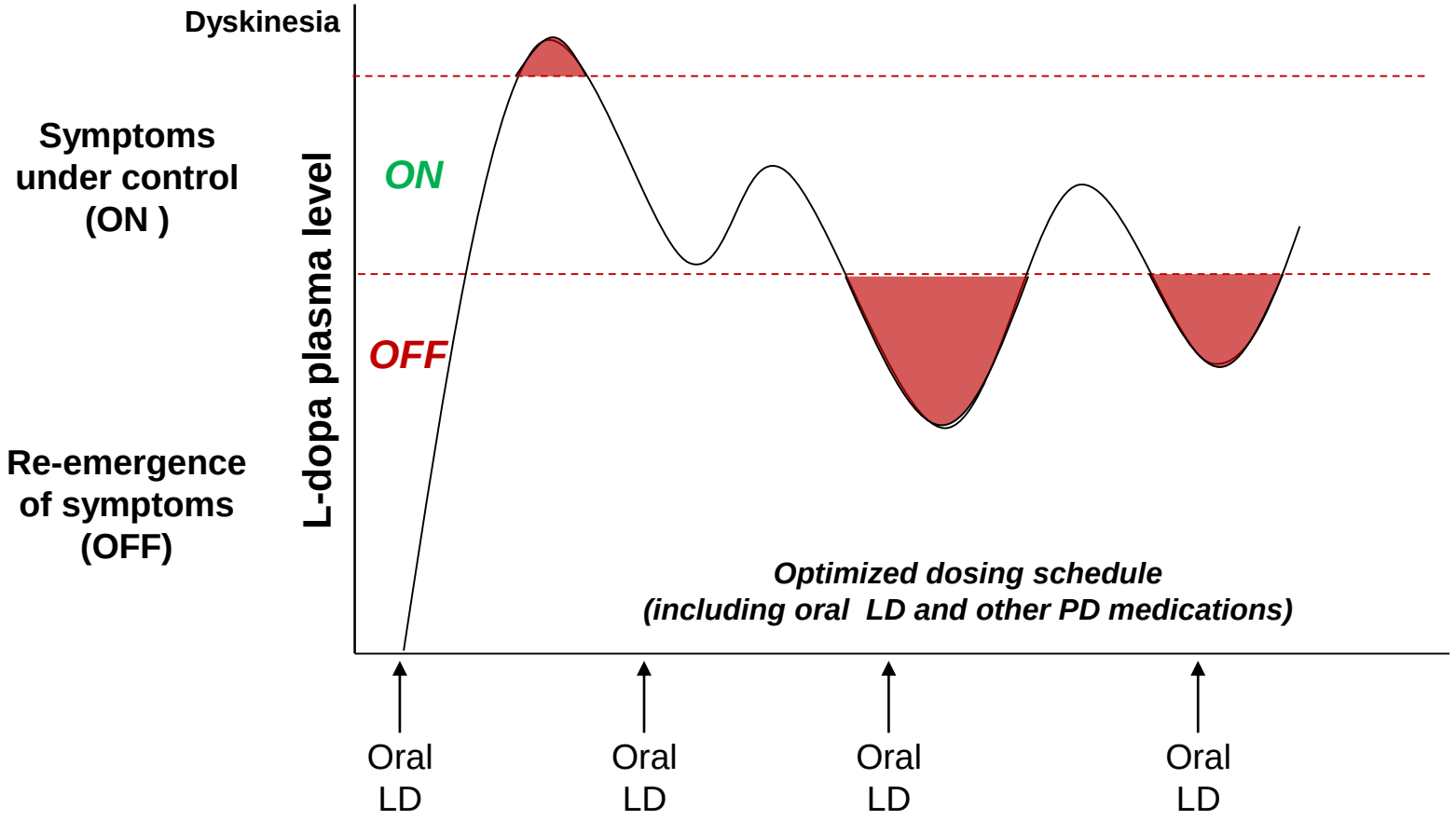
- PD symptoms become increasingly difficult to control with oral levodopa therapy as the disease progresses
- OFF periods, defined as re-emergence of PD symptoms, can occur throughout the day and be unexpected
- Re-emergence of PD symptoms is a major concern for people with PD and can be disruptive

Burden of OFF Periods

- In a survey of ~3,000 individuals with PD, most experienced at least two OFF periods daily, each with an average duration of 30–60 minutes[1]
- OFF periods[2,3] interrupt ability to function throughout the day

1 The Michael J. Fox Foundation Survey of Parkinson's Patients' Off Time Experience, July 2014.
2 Hechtner MC et al. Parkinsonism Relat Disord 20, 969-974 (2014).
3 Brown RG et al. J Psychosom Res 78(2),143-148 (2015).

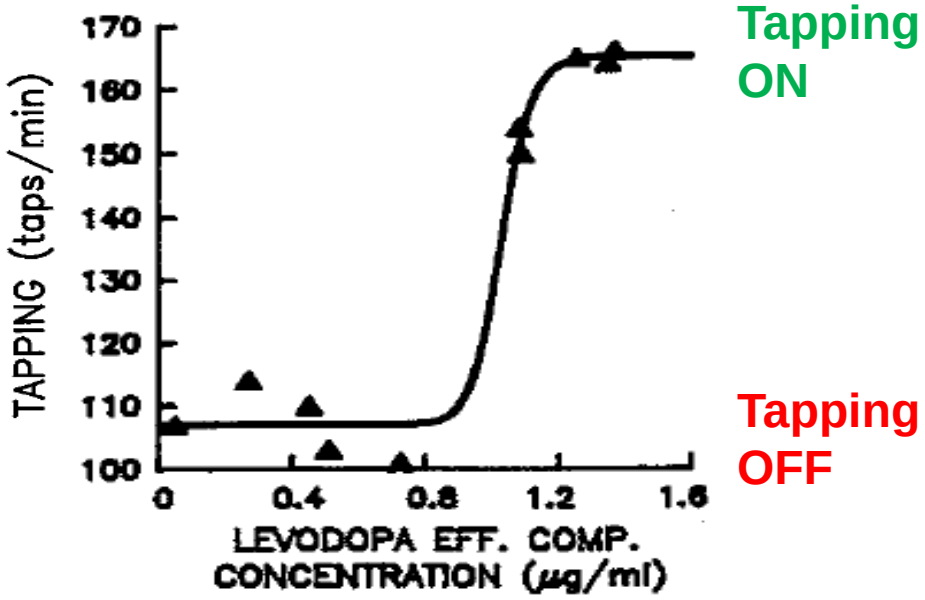
OFF Periods Associated with Variations in Plasma Levodopa



- **Over time, patients may experience OFF Periods despite being optimized on oral LD and other baseline PD medications**
- **Patients may experience OFF periods due to wearing off of LD, delayed onset of LD, or an incomplete response**

Stacy M et al. Mov Disord. 2005;20:726-733. 2. Stacy M et al. 2009. www.medscape.org/viewarticle/701955. Accessed October 2016. Permission for use of adapted figure granted by John Wiley & Sons, Inc., for Stacy M et al. Mov Disord. 2005;20:726-733. © 2005 Movement Disorder Society.

Oral Levodopa is Highly Effective and the Gold Standard…



At L-dopa therapeutic threshold:

Small change in plasma level

Large change in motor function

300-400 ng/ml can bridge

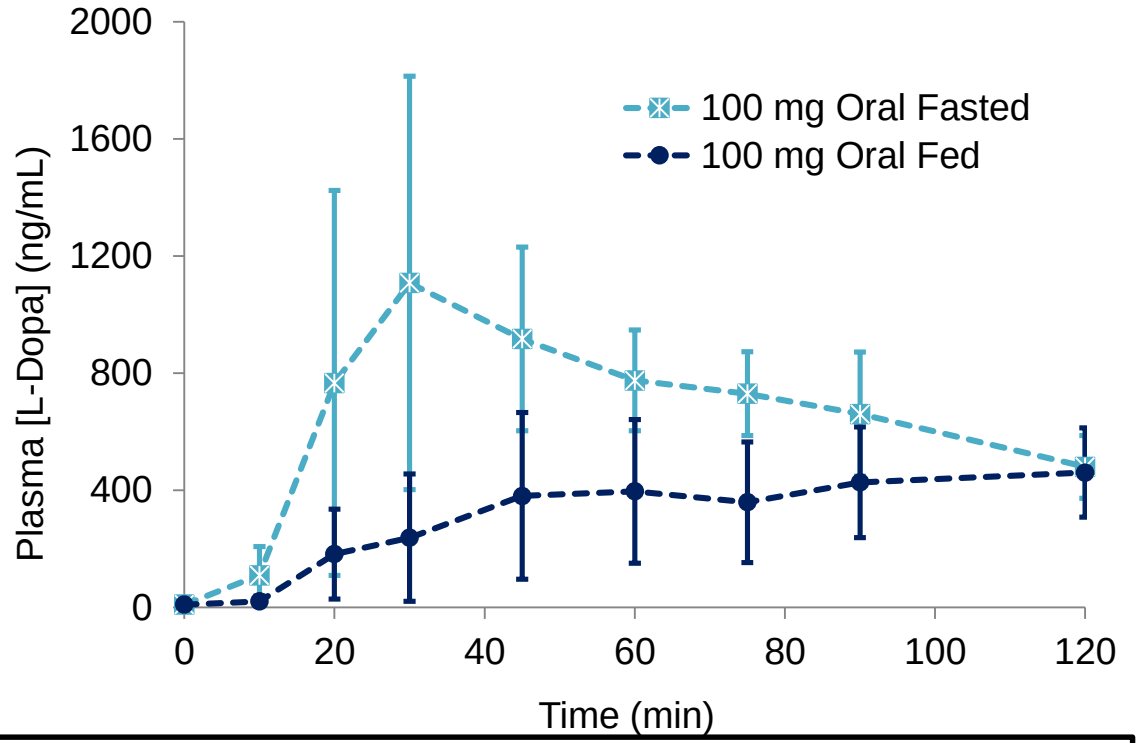
Source: Contin, M, et al. Pharmacodynamic modeling of oral levodopa: Clinical application in Parkinson's disease. Neurology 43, 367-371 (1993).

…but There is Inherent Variability of the Oral Route…

Barriers to getting oral L-dopa to the CNS

Oral levodopa related challenges
- Site specific intestinal active transport
- Competitive amino acid absorption
- First pass metabolism

Parkinson's related challenges
- Erratic and slowed gastric emptying
- Difficulty swallowing
- Exacerbated food effect



"Variation in levodopa concentration is the determining factor for motor fluctuations."
- Nyholm, 2002

Error bars represent standard deviations. Source: 001 clinical study

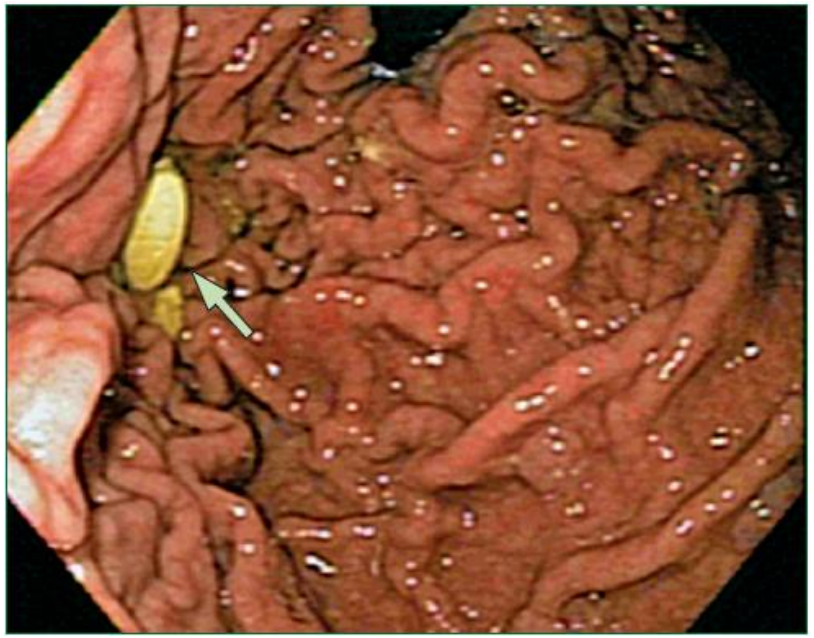
Nyholm, D, Lennernäs, H, Gomes-Trolin, C, and Aquilonius, S. Levodopa Pharmacokinetics and Motor Performance During Activities of Daily Living in Patients with Parkinson's Disease on Individual Drug Combinations. Clinical Neuropharmacology 25, 89-96 (2002).

…Exacerbated by Parkinson's Disease Effects

Barriers to getting oral L-dopa to the CNS

Oral levodopa related challenges
- Site specific intestinal active transport
- Competitive amino acid absorption
- First pass metabolism

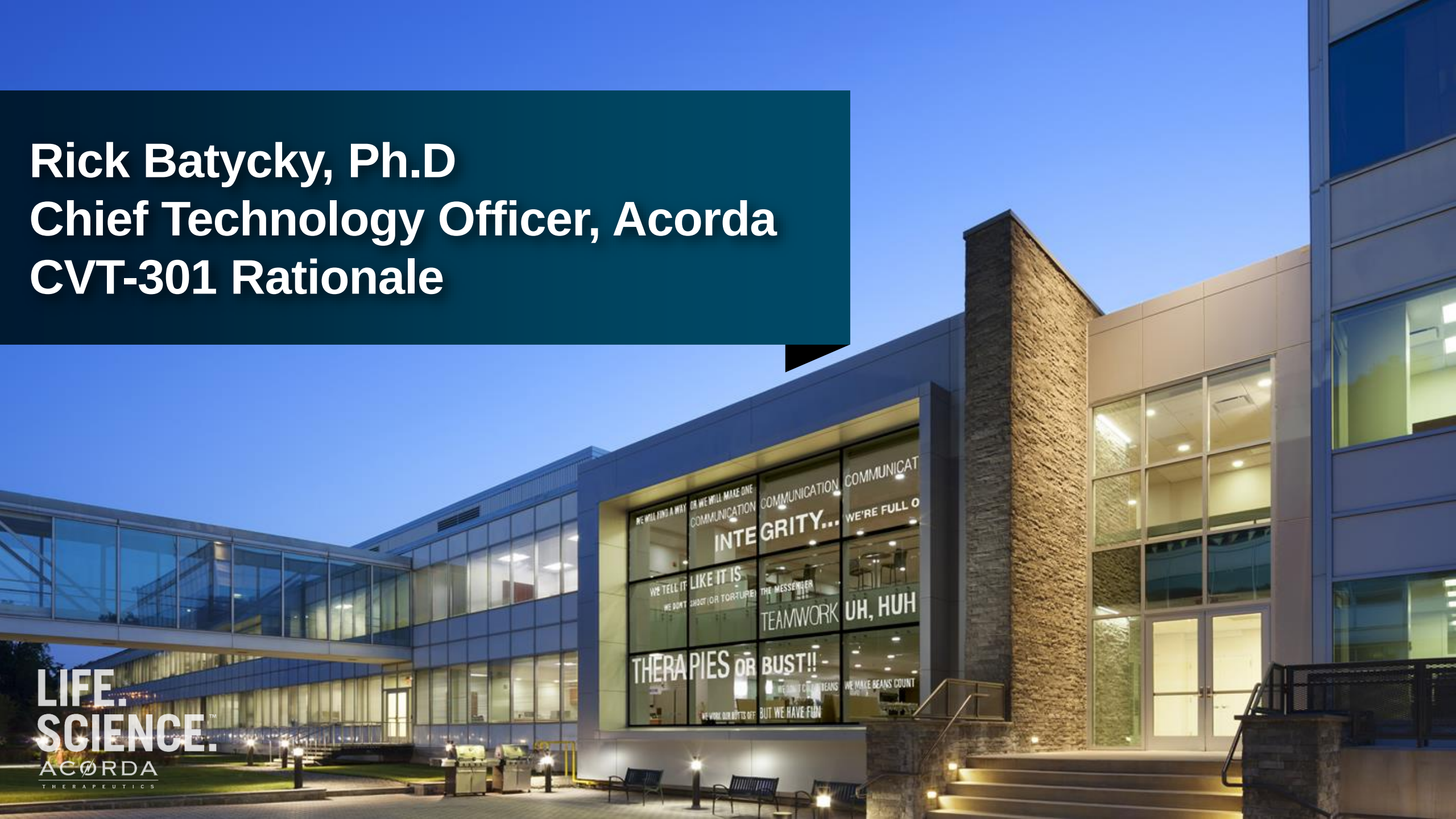
Parkinson's related challenges
- Erratic and slowed gastric emptying
- Difficulty swallowing
- Exacerbated food effect



Delay in Gastric Emptying: Arrow points to a carbidopa tablet remaining intact in a patient's stomach about 1.5 hours after intake

Photo: Fasano A, Visanji, NP, Liu, LW, Lang, AE, & Pfeiffer, RF. Gastrointestinal dysfunction in Parkinson's disease. Lancet Neurology 14, 625-39 (2015).

Rick Batycky, Ph.D
Chief Technology Officer, Acorda
CVT-301 Rationale



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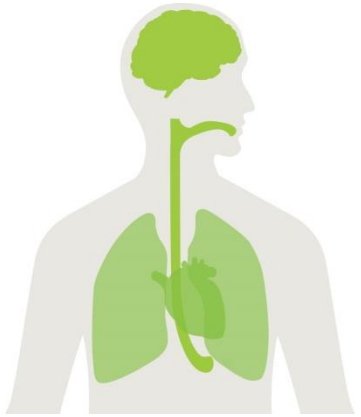
The Pulmonary Route Avoids the GI Tract

Unlike oral delivery, pulmonary delivery provides more direct route to CNS

Oral Delivery

- Esophagus
- Stomach
- Intestine
- Liver
- Heart
- Lungs
- Heart
- Brain



Pulmonary

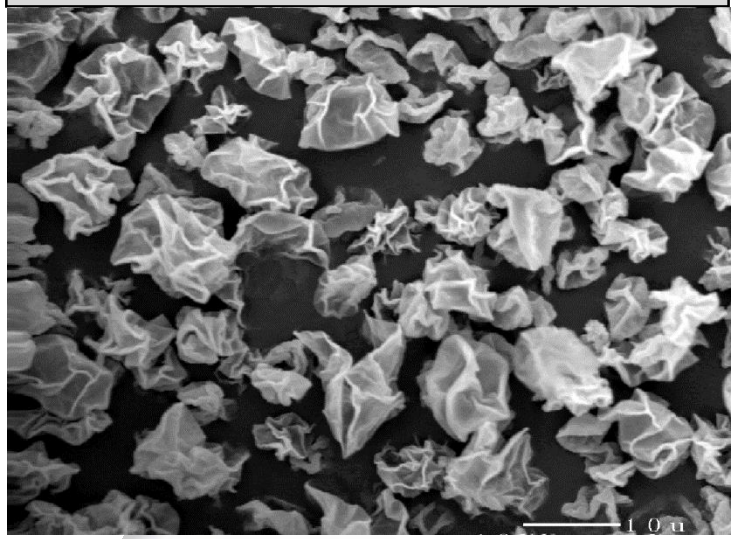
- Lungs
- Heart
- Brain

Potential Benefits of Pulmonary Delivery

- Efficient and rapid path for systemic delivery via the bloodstream
- Bypasses the GI tract
  - Avoids first pass metabolism
  - Increases the amount of available drug to the brain

Acorda's ARCUS® Platform for LD Delivery

Proprietary Large, Porous Particles



ARCUS® was designed to:

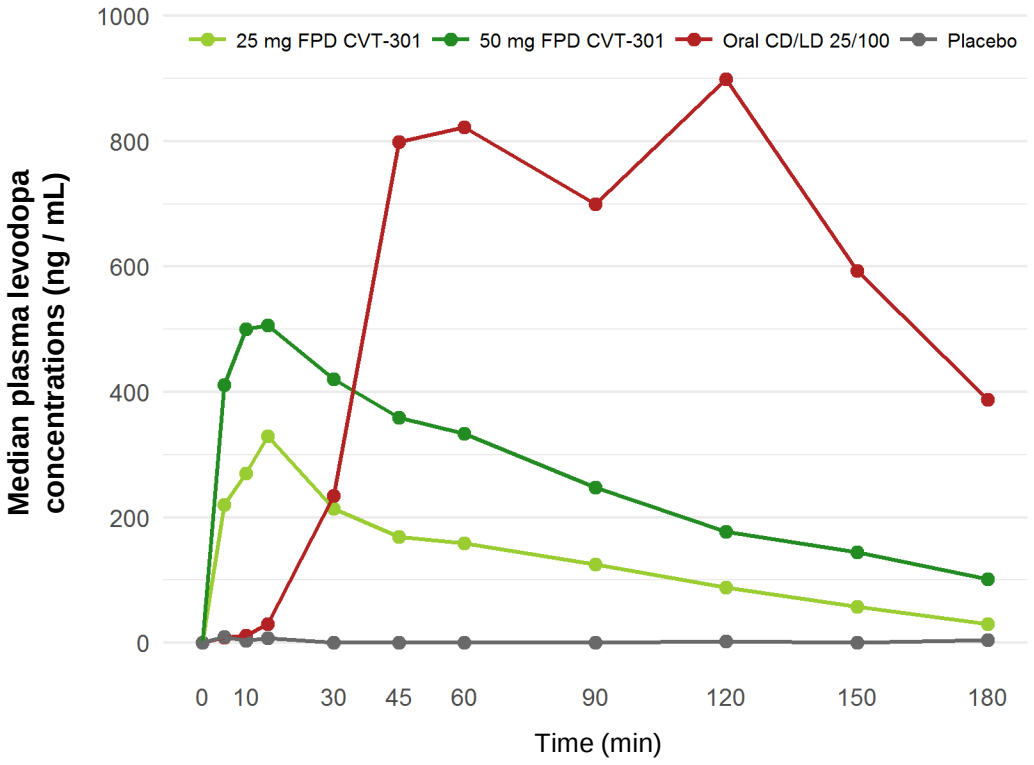
- **Deliver large doses**
- **Achieve high efficiency**
- **Deliver doses across flow rates**

Edwards, D et al. Large Porous Particles for Pulmonary Drug Delivery. Science 276, 1868-1871 (1997).

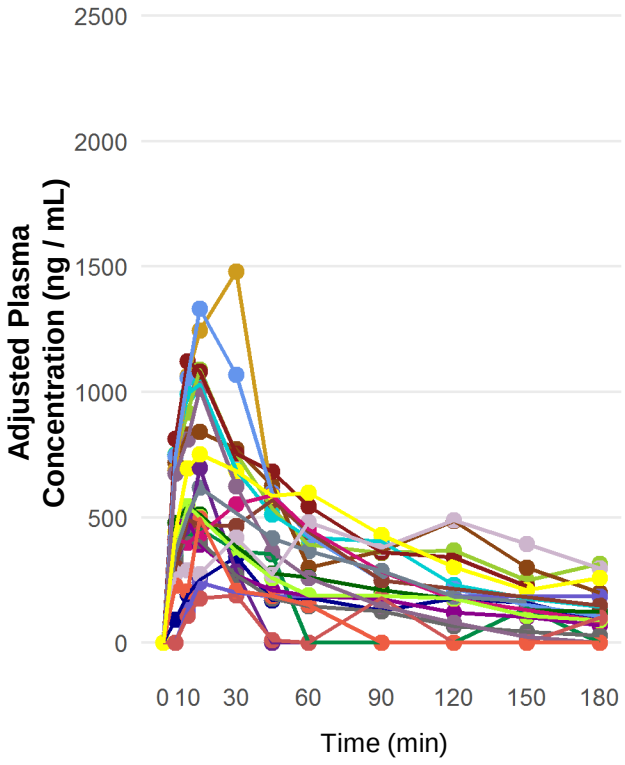
Lipp M, Batycky, R, Moore, J, Leinonen, M, Freed, M. Preclinical and clinical assessment of inhaled levodopa for OFF episodes in Parkinson's disease. Science Translational Medicine 8, 360ra136, 1-10 (2016).

CVT-301 Showed C_{max} Within 30 Minutes

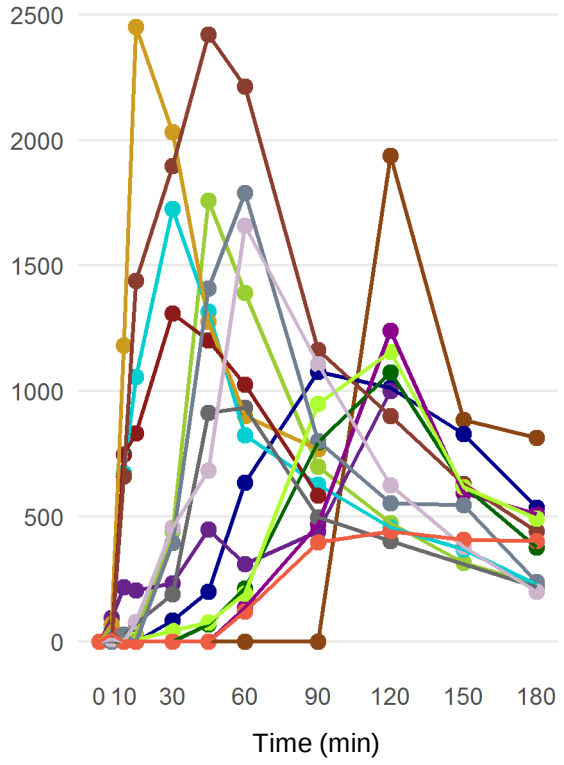
CVT-301 Pharmacokinetics vs. Oral
Median Curves



Inhaled CVT-301 (50 mg FPD)
Individual Curves



Oral CD/LD (25 / 100 mg)
Individual Curves



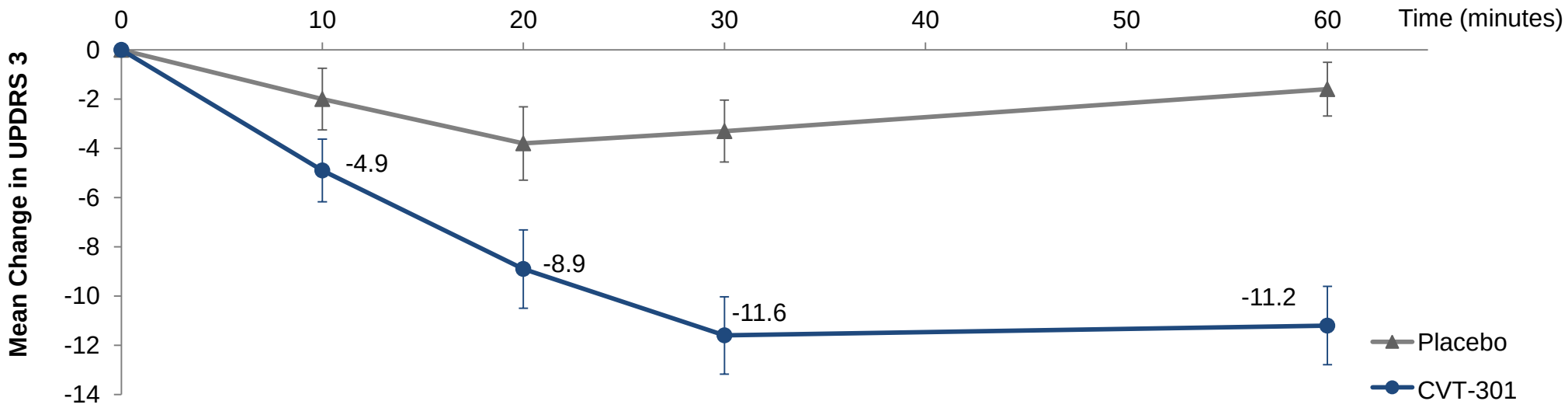
Source: CVT-301-002 study (conducted in PD patients)

Note: Formulation in 002 used different fill weights as compared to comparable doses in studies 004 or 005; 60 mg and 84 mg doses used in studies 004 and 005 reflect 25 mg and 50 mg equivalent fine particle doses (FPD), respectively

Right: Fasted oral Carbidopa / Levodopa: 25 mg / 100 mg

Phase 2B Results

CVT-301-003 Study: UPDRS3 Change from Baseline at Week 4 (82.8 mg CVT-301 vs. Placebo)

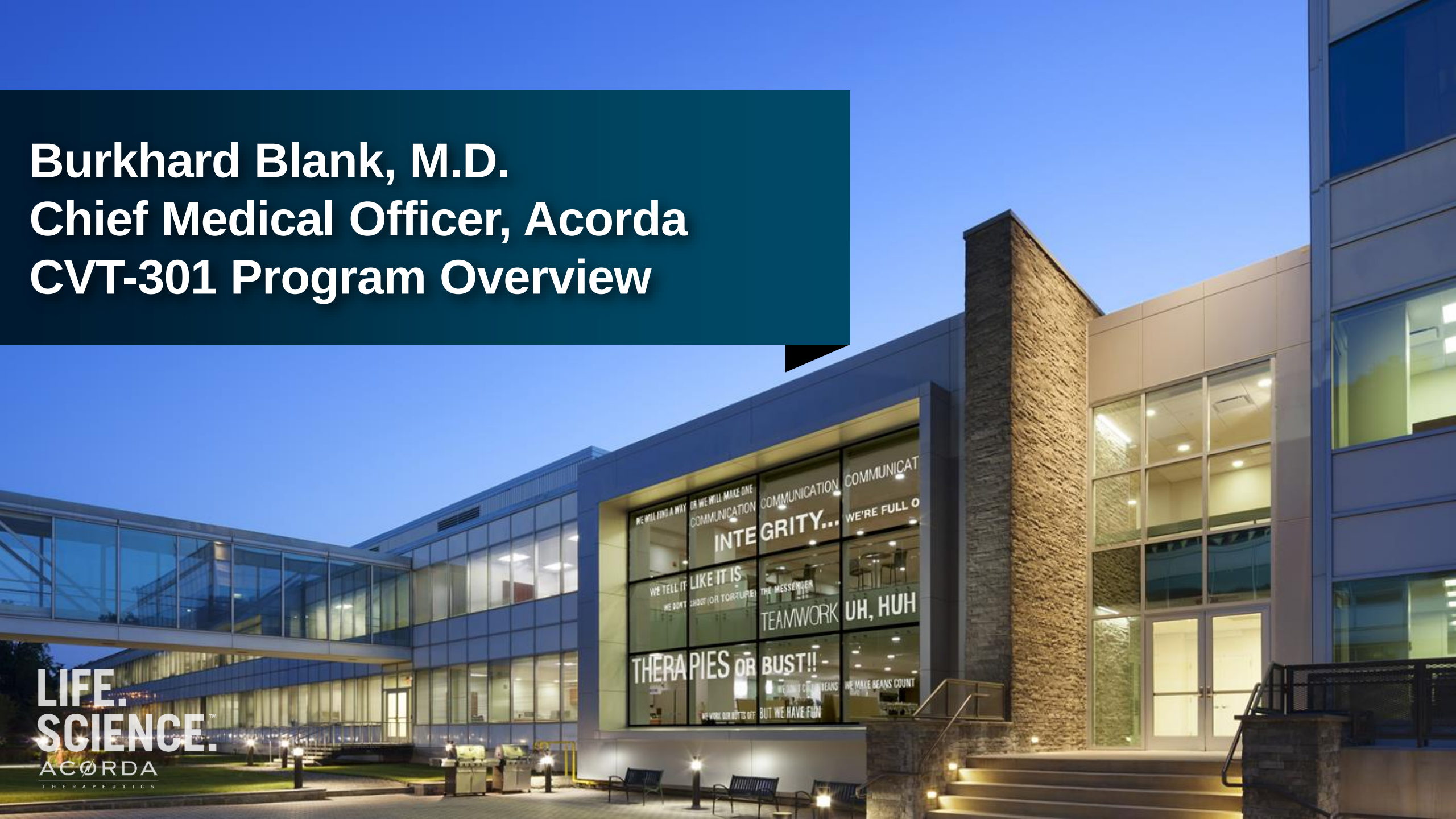


	10 min	20 min	30 min	60 min
Diff vs Pbo	-3.56	-5.68	-8.43	-9.59
p-value*	0.0309	0.0068	<0.0001	<0.0001

* Nominal p-values; error bars are standard errors

Note: Formulation in 003 high dose used lower fill weight (82.8 mg) as compared to comparable dose in studies 004 or 005 (84 mg); both formulations reflect 50 mg equivalent fine particle doses

Burkhard Blank, M.D.
Chief Medical Officer, Acorda
CVT-301 Program Overview



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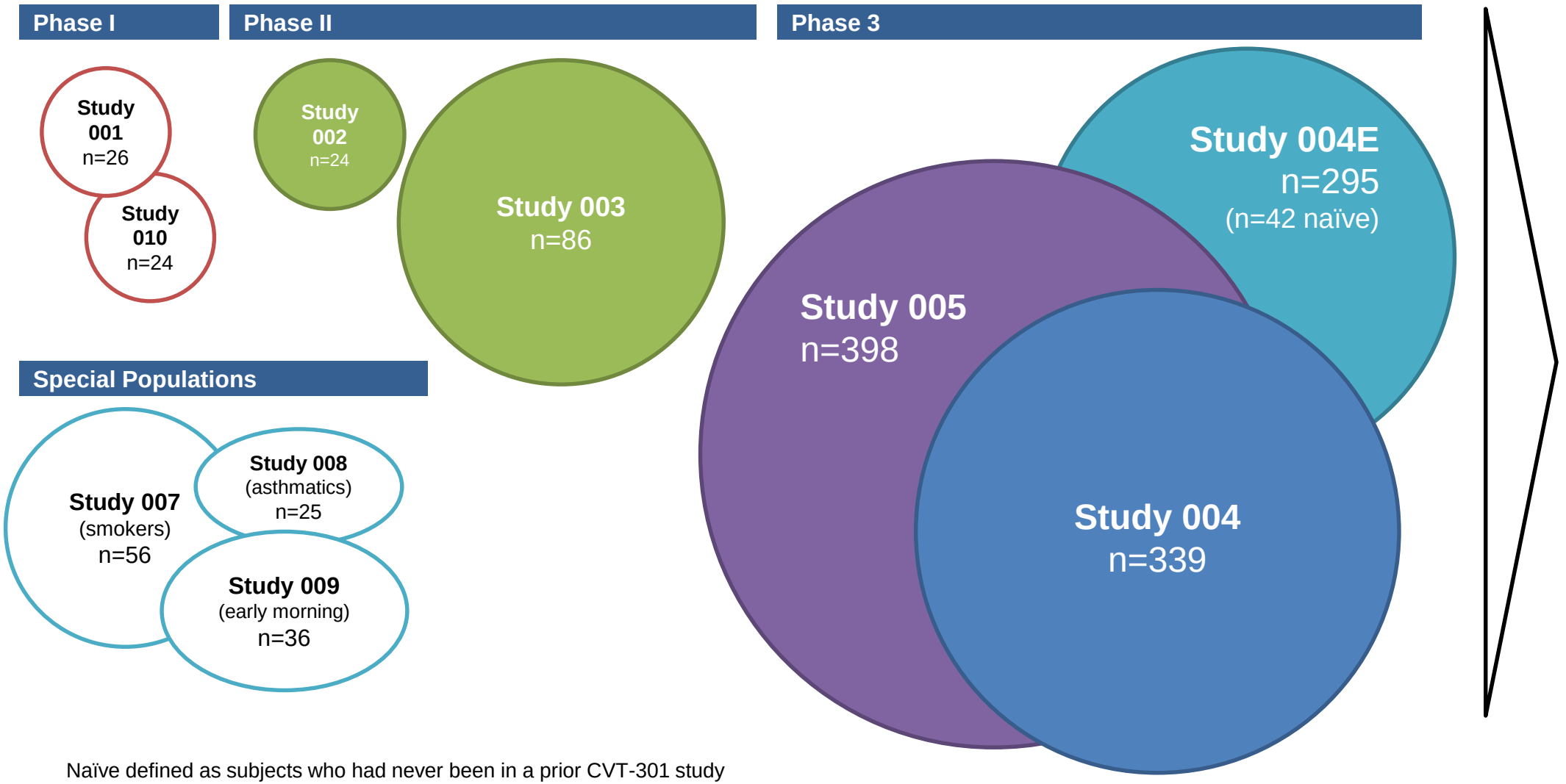
CVT-301 - A Comprehensive Development Program



Greater than 1,000 subjects studied in the CVT-301 clinical program

Naïve defined as subjects who had never been in a prior CVT-301 study

CVT-301 Phase 3 - Current Status

Study complete

Study ongoing

	Current Status	Regulatory Plan
CVT-301-004 (n=339)	• Complete	• Will be submitted complete with initial NDA submission
CVT-301-004E (n=295)	• Ongoing • Interim data as of February 10th, 2017 – 94 (32%) completed month 6 – 44 (15%) completed month 12	• Datasets as of February 10th 2017 will comprise the initial NDA submission • To submit updated interim data at 120 day safety update
CVT-301-005 (n=398)	• Ongoing • Interim data as of February 10th, 2017 – Nearly 100% completed month 9 – 187 (46%) completed month 12	• Datasets as of February 10th 2017 will comprise the initial NDA submission • Complete data to be submitted at 120 day safety update
Special Populations CVT-301-007, 008, 009 (n=117)	• Complete	• Will be submitted complete with initial NDA submission

Design of Phase 3 Program

CVT-301-004

- Randomized, double-blind, placebo controlled multicenter (US/Can: 79%, EU*: 21%)
- 1:1:1 randomization:
  - Placebo
  - Dose level 1 (DL1): 60 mg (35 mg FPD)
  - Dose level 2 (DL2): 84 mg (50 mg FPD)
- Sample size: 339

CVT-301-004E (Interim Analysis)

- Randomized, dose-level blinded, multicenter, uncontrolled (US/Can: 69%, EU*: 31%)
- CVT-301 60 mg and 84 mg doses randomized 1:1
- Sample size: 295

CVT-301-005 (Interim Analysis)

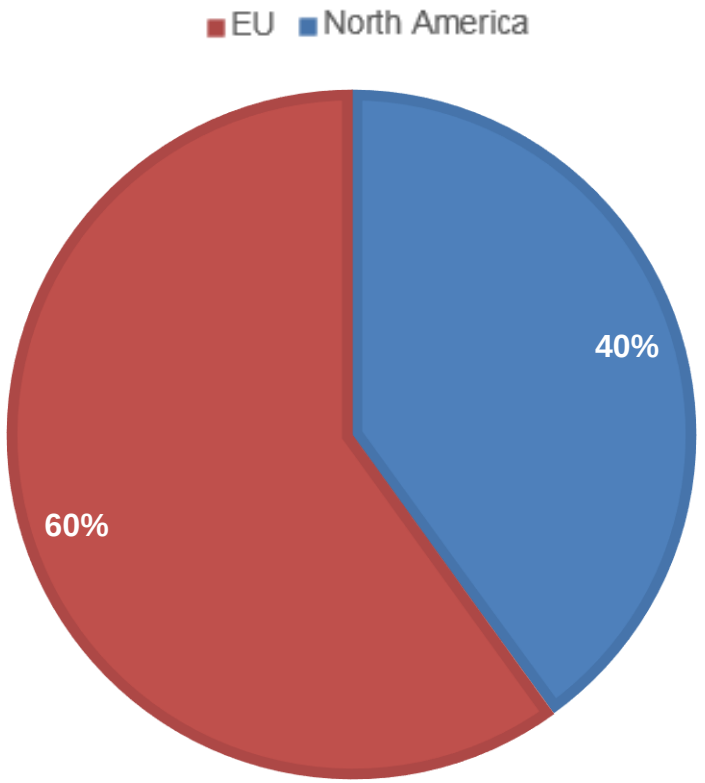
- Randomized, open-label, multicenter, observational control (US: 7%, EU*: 93%)
- CVT-301 84 mg to Observational Cohort, randomized 2:1
- Sample size: 398

- Randomization stratified for all studies by:
  - H&Y in ON state <2.5 vs ≥2.5
  - FEV_1 <60% or FEV_1/FVC <70% vs FEV_1 ≥60% and FEV_1/FVC ≥70%

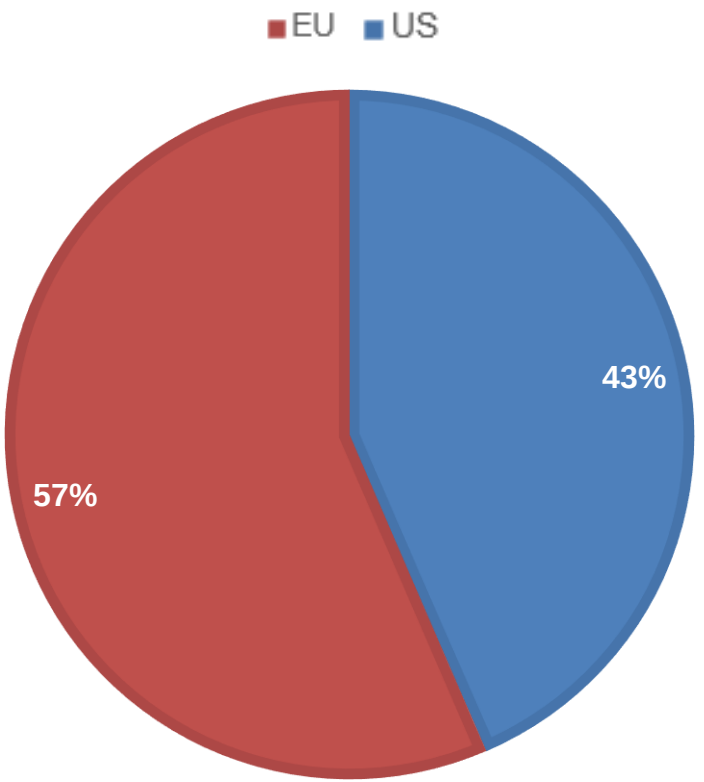
* Including Israel

Geographic Mix - 004 + 005 Pooled Population US/EU Prevalence

CVT-301-004 + CVT-301-005



US vs. EU Prevalence



In CVT-301-004 + 005, North America was predominantly US patients (> 95%); US and Canada represented 67% of CVT-301-004E patients naïve (n=42) to the program, not included in the above

Source: Decision Resources

Key Inclusion and Exclusion Criteria
Similar Criteria Used Across the Phase 3 Studies

Inclusion	Exclusion
Males/females 30-85 years of age	Dyskinesia interfering with performing study procedures
Idiopathic PD, H&Y 1-3 in the ON state	Known contraindications to CD/LD
Daily OFF ≥2 hrs per day (excludes morning OFF)	Undergone deep brain stimulation (DBS)
CD/LD regimen	History of asthma, COPD, other chronic lung disease*
PD medications stable ≥4 wks prior to screen**	Concomitant use of apomorphine HCl
UPDRS 3 ≥25% between ON & OFF at screening	
MMSE ≥25	
Able to perform spirometry in ON & OFF	
Screening lung function tests***	

* Within the past 5 years

** Patients on Rytary (CD/LD) required stable medication for ≥ 6 weeks prior to screen

*** FEV1 ≥ 50% predicted, FEV1/FVC > 60% in ON state

Baseline Parkinson's Disease Characteristics

Baseline PD Characteristics

	CVT-301-004	CVT-301-005
H&Y ≥ 2.5	35%	53%
PD Duration	8.3 years	9.3 years
Baseline LD Dosage	828 mg	808 mg
Frequency of OFF Periods	3.5	3.7
Avg OFF Time	5.5 hours	5.6 hours

Population experienced average of > 3 OFF periods daily in spite of existing levodopa treatment averaging > 800 mg daily

Concomitant Medications

	CVT-301-004	CVT-301-005
Dopamine agonists	206 (61%)	299 (75%)
MAO-B inhibitors	122 (36%)	152 (38%)
Amantadine (and equivalents)	70 (21%)	117 (29%)
COMT inhibitors	74 (22%)	131 (33%)

Most patients studied were on multiple Parkinson's disease therapies in addition to levodopa

Peter LeWitt, M.D.
CVT-301-004 Study Overview

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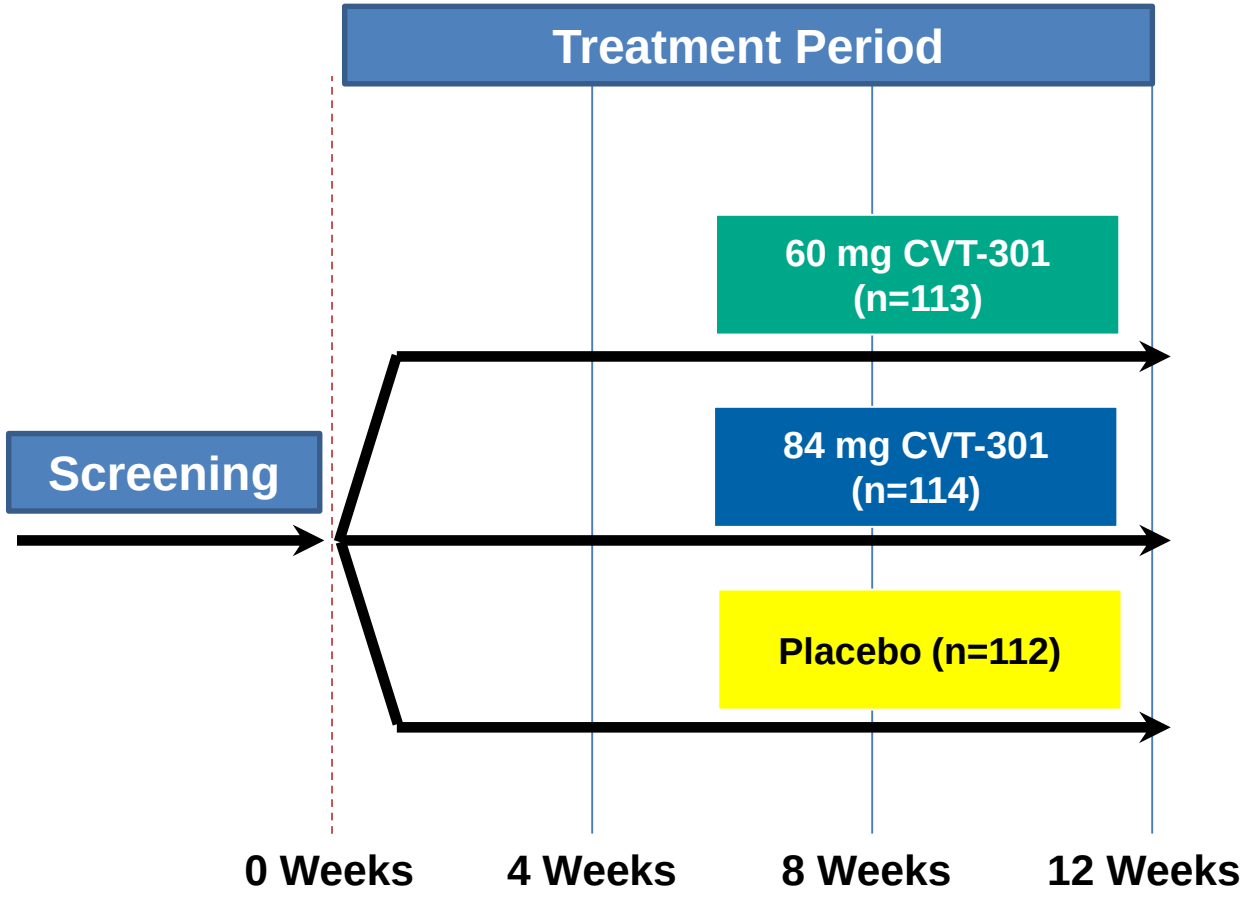
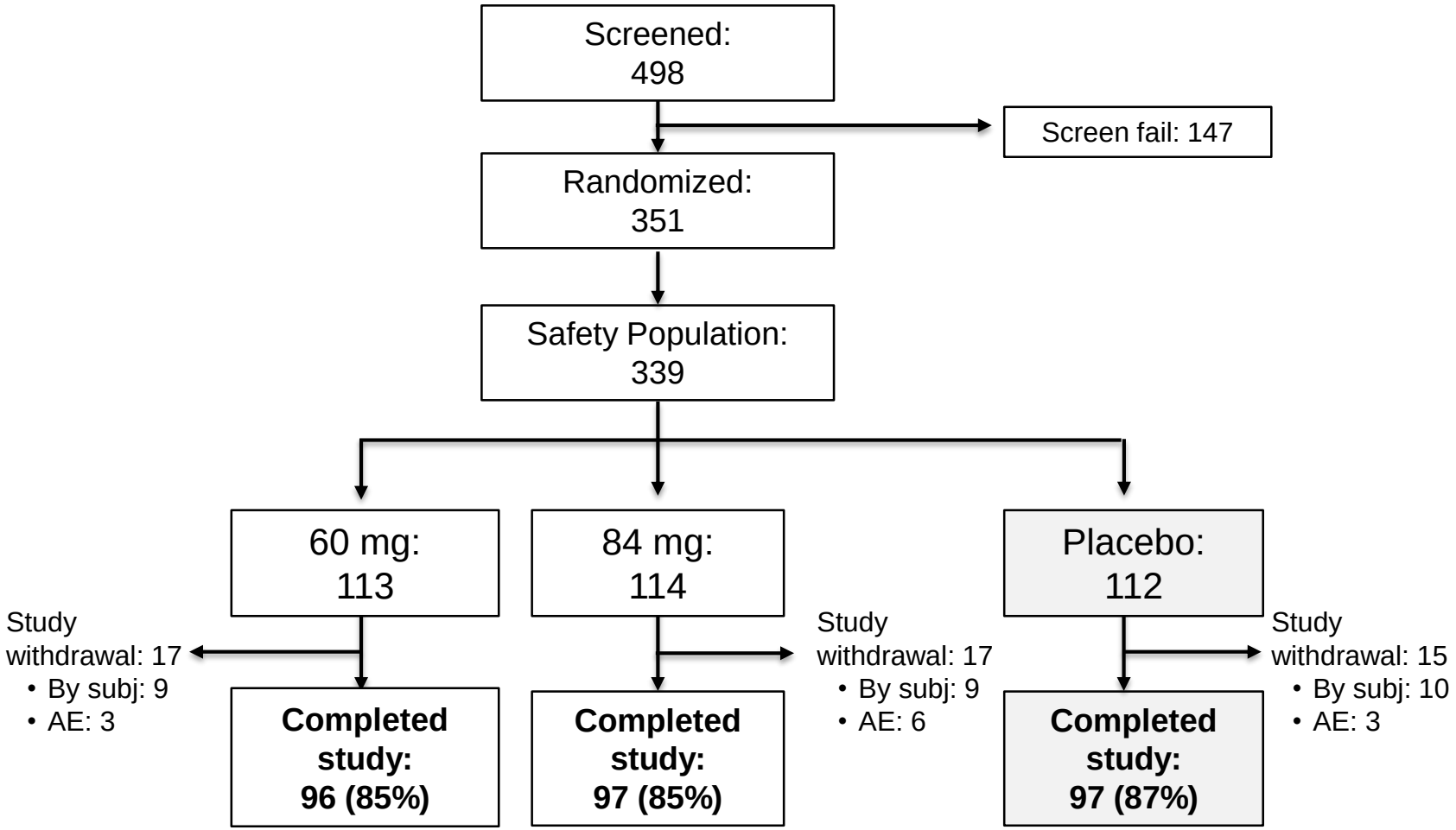
CVT-301-004 Study Design



- **3 month study, parallel group design**
  - Patients randomized to CVT-301 (60 mg or 84 mg) or placebo
  - Patients dosed themselves in-clinic while in the OFF state
  - UPDRS3 measurements were conducted in-clinic, in addition to clinician assessed dyskinesia
  - In-clinic visits every month
- **Inhaler and capsules taken home: patient instructed to use CVT-301 as needed**
  - PD diary collected over course of the trial

CVT-301-004 Subject Disposition

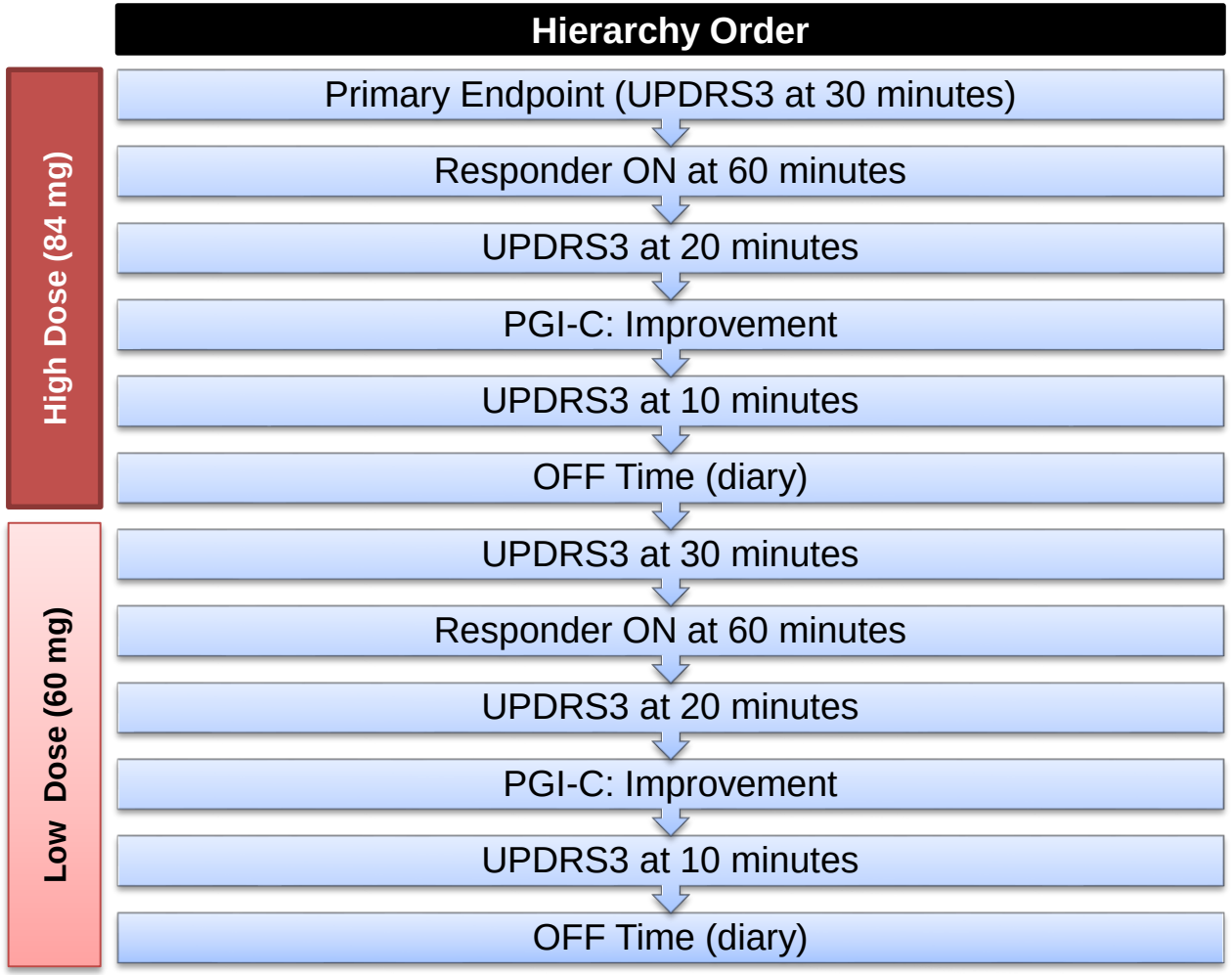


- **Withdrawal rate (any reason):**
  - 60 mg CVT-301: 15%
  - 84 mg CVT-301: 14%
  - Placebo: 13%
- **Rate of withdrawal due to AEs:**
  - 60 mg CVT-301: 3%
  - 84 mg CVT-301: 5%
  - Placebo: 3%
- **Cough:**
  - 3 patients out of 227 patients (1.3%) exposed to CVT-301 discontinued due to cough

CVT-301-004
Baseline Characteristics

		CVT-301-004		
		CVT-301 60 mg	CVT-301 84 mg	Placebo
Parkinson's Disease Characteristics	Mean age (yrs)	63.9	63.5	62.6
	Sex (male), %	70.8%	72.8%	76.8%
	H&Y ≥2.5 (More Severe)	34.5%	36.8%	33.9%
	Duration of PD (yrs)	8.7 years	8.0 years	8.1 years
	CD/LD treatment (yrs)	7.1 years	6.3 years	6.8 years
	Daily Levodopa (mg)	822.7	818.6	841.4
	CD/LD (doses)	5.0	5.0	5.2
	Daily OFF Periods incl. AM	3.5	3.6	3.3
	Daily OFF incl. AM (hrs)	5.6	5.4	5.6

CVT-301-004
Hierarchy Order of Endpoints



- **Order of hierarchy was set based on likely probability of success**
  - Guided by Phase 2b results

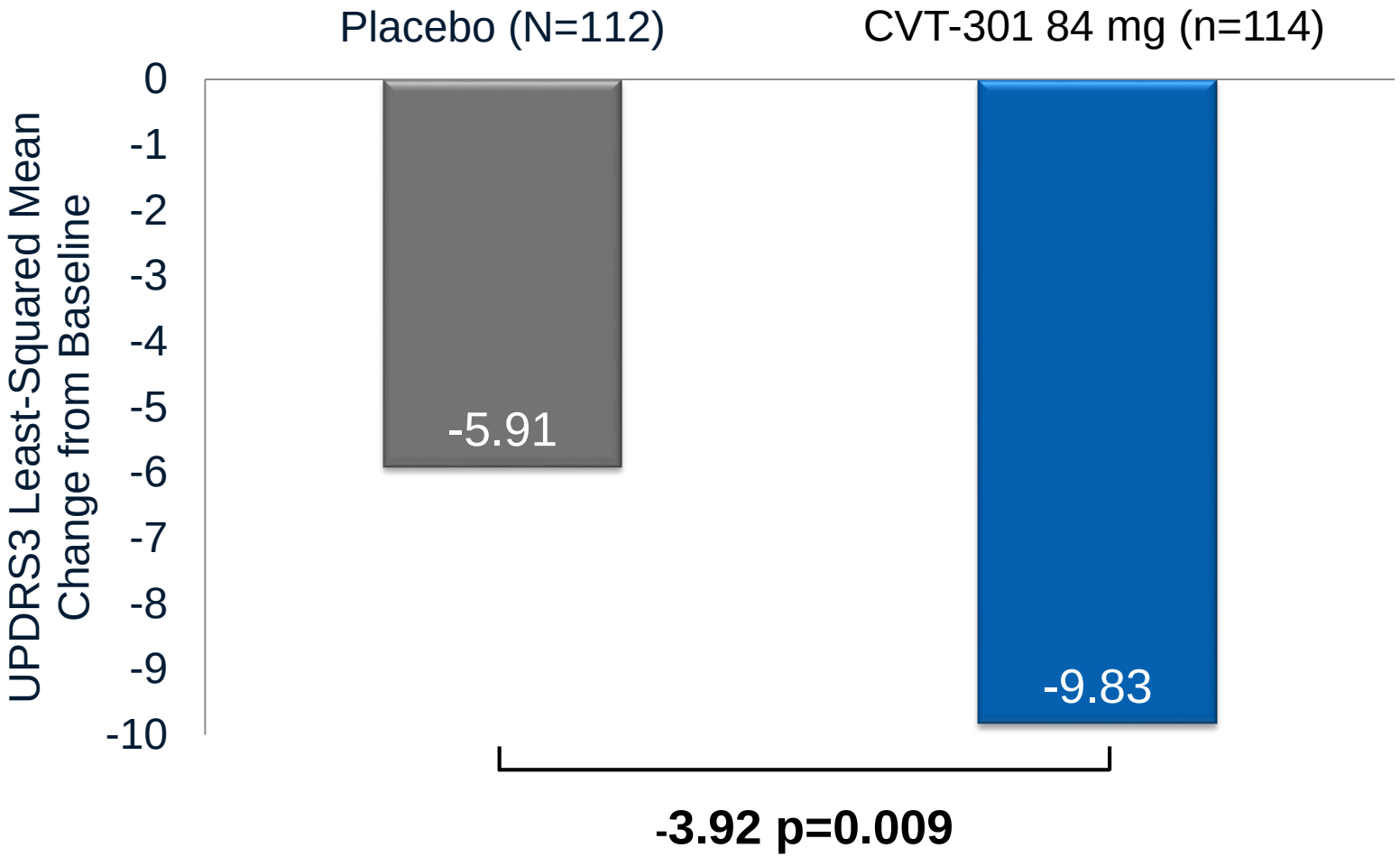
CVT-301-004
Primary and Secondary Endpoints

Endpoint	Step	84 mg vs PBO			Step	60 mg vs PBO	
		Δ	p-value			Δ	p-value
Change UPDRS 3 at 30 min	**1 (Primary)**	**-3.92**	**0.009****		7	-3.07	0.039*
% Responder ON at 60 min	2	21.60	**0.003****		8	19.50	0.006*
Change UPDRS 3 at 20 min	3	-2.55	0.062		9	-1.98	0.147
% Patients improved on PGI-C	4	25.00	<0.001*		10	15.20	0.026*
Change UPDRS 3 at 10 min	5	-2.26	0.046*		11	-0.97	0.387
Change PD Diary OFF time	6	-0.01	0.975		12	0.10	0.722

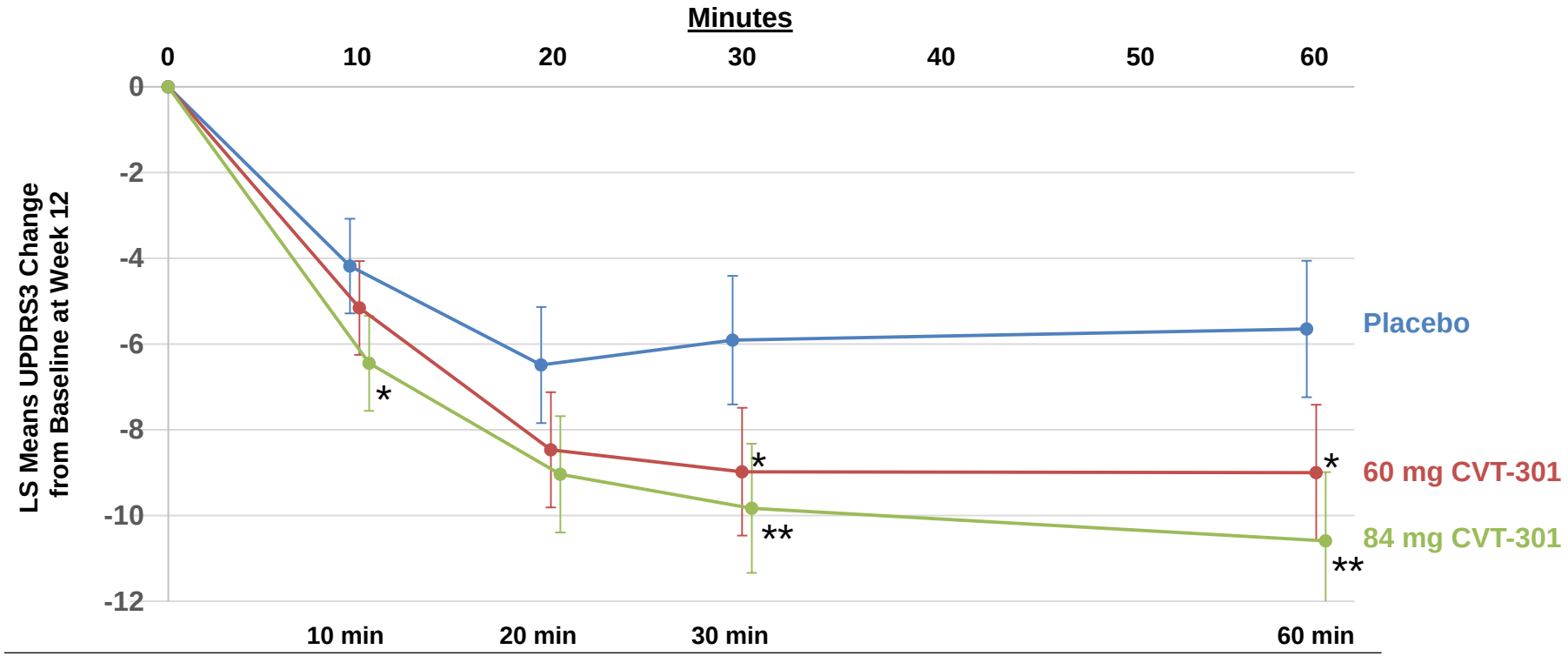
** Statistically significant on a nominal and adjusted basis

* Statistically significant on a nominal basis only

Primary Endpoint Achieved
Change from Pre-dose UPDRS 3 30 Min at Week 12



CVT-301-004
UPDRS3 Change from Baseline at Week 12: CVT-301 vs. Placebo



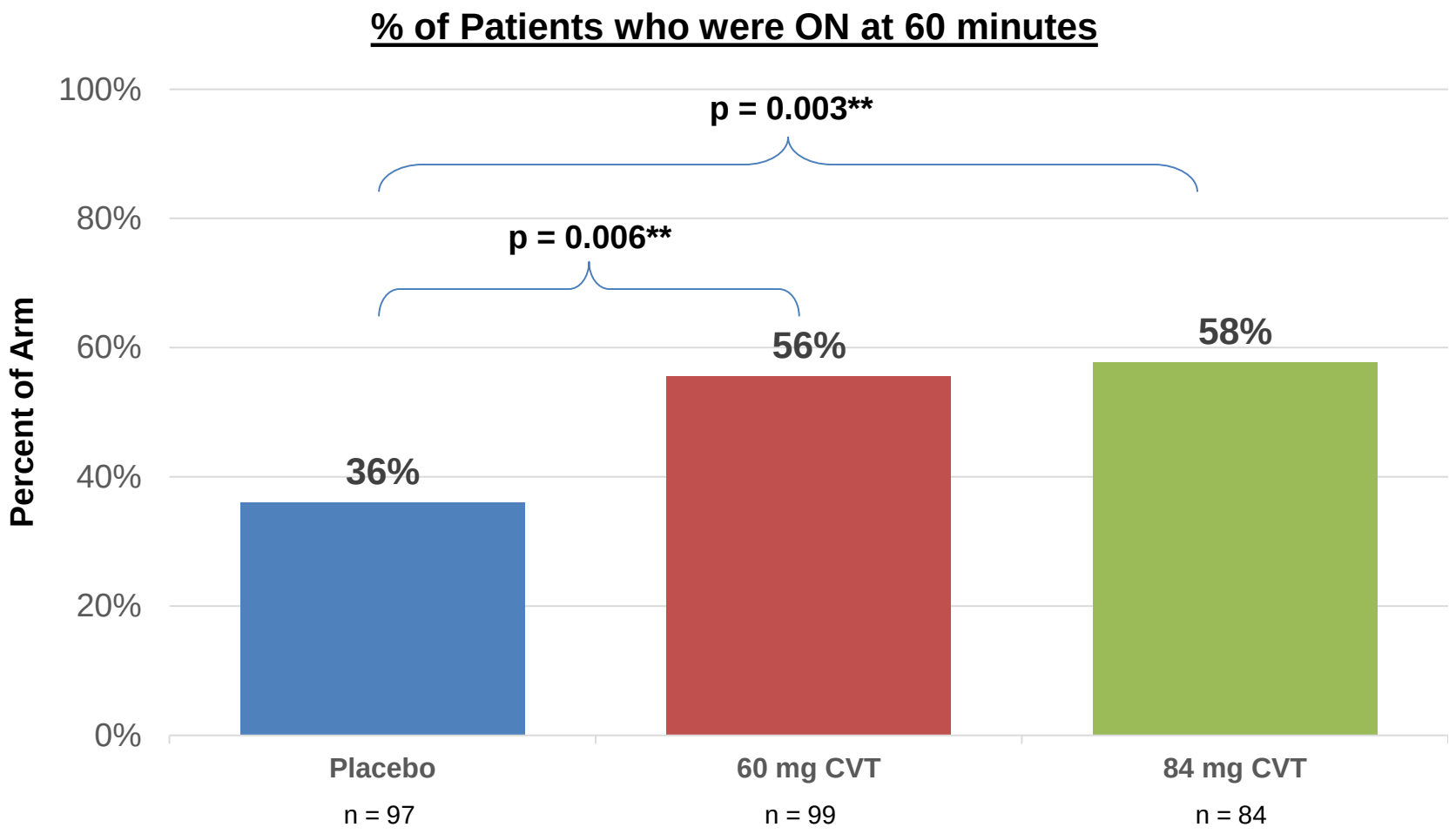
	10 min	20 min	30 min	60 min
Δ 60 mg vs. Pbo:	**-0.97**	**-1.98**	**-3.07**	**-3.35**
p-value:	p = 0.387	p = 0.147	p = 0.039*	p = 0.035*
Δ 84 mg vs. Pbo:	**-2.26**	**-2.55**	**-3.92**	**-4.94**
p-value:	p = 0.046*	p = 0.062	p = 0.009**	p = 0.002**

- **Primary endpoint achieved (84 mg dose vs. placebo at 30 minutes)**
- **Dose-dependent response observed**
- **Effect persisted through 60 minutes**

Nominal P-values: * p < 0.05, ** p < 0.01, *** p < 0.001

Error bars indicate standard errors; time points staggered for readability; changes vs. placebo represent least squared means changes

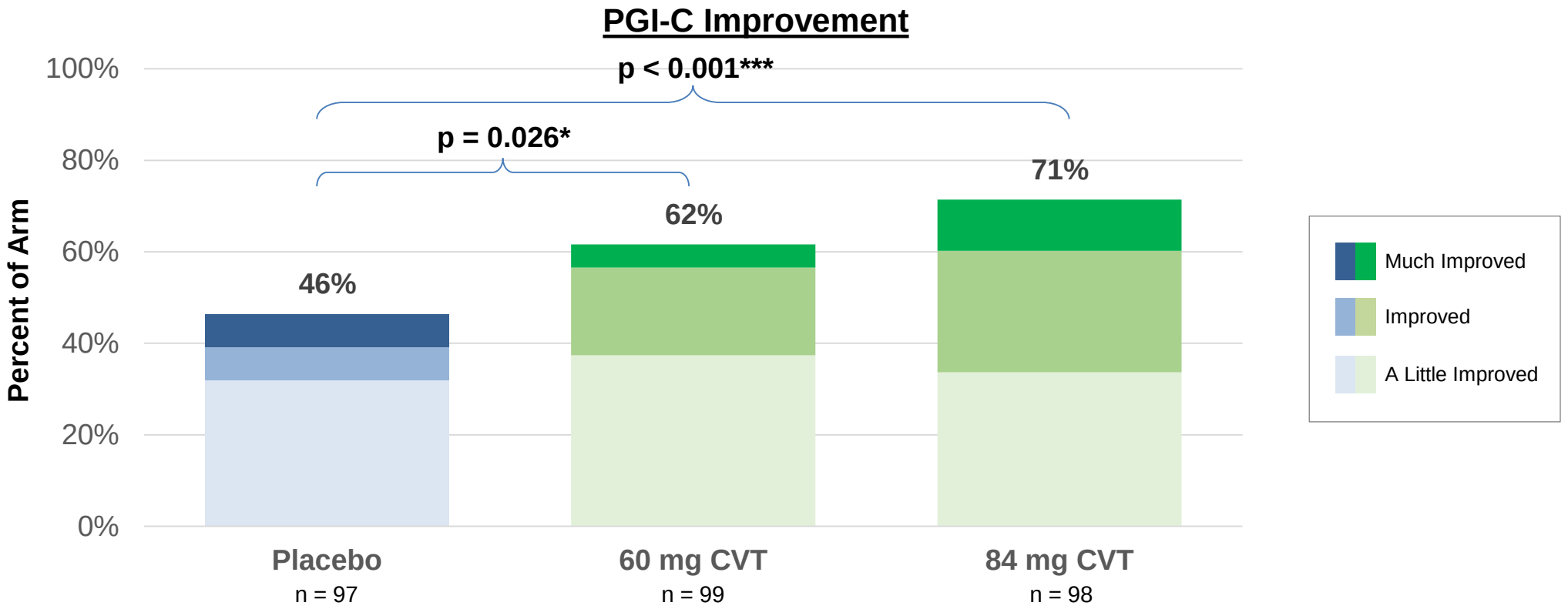
CVT-301-004
Significantly More CVT-301 patients Turned ON vs. Placebo at Week 12



Nominal P-values: * p < 0.05, ** p< 0.01, *** p < 0.001

Note: Assumes worst case imputation for missing data if visit occurred

CVT-301-004
Secondary Endpoints: PGI-C Improvement at Week 12



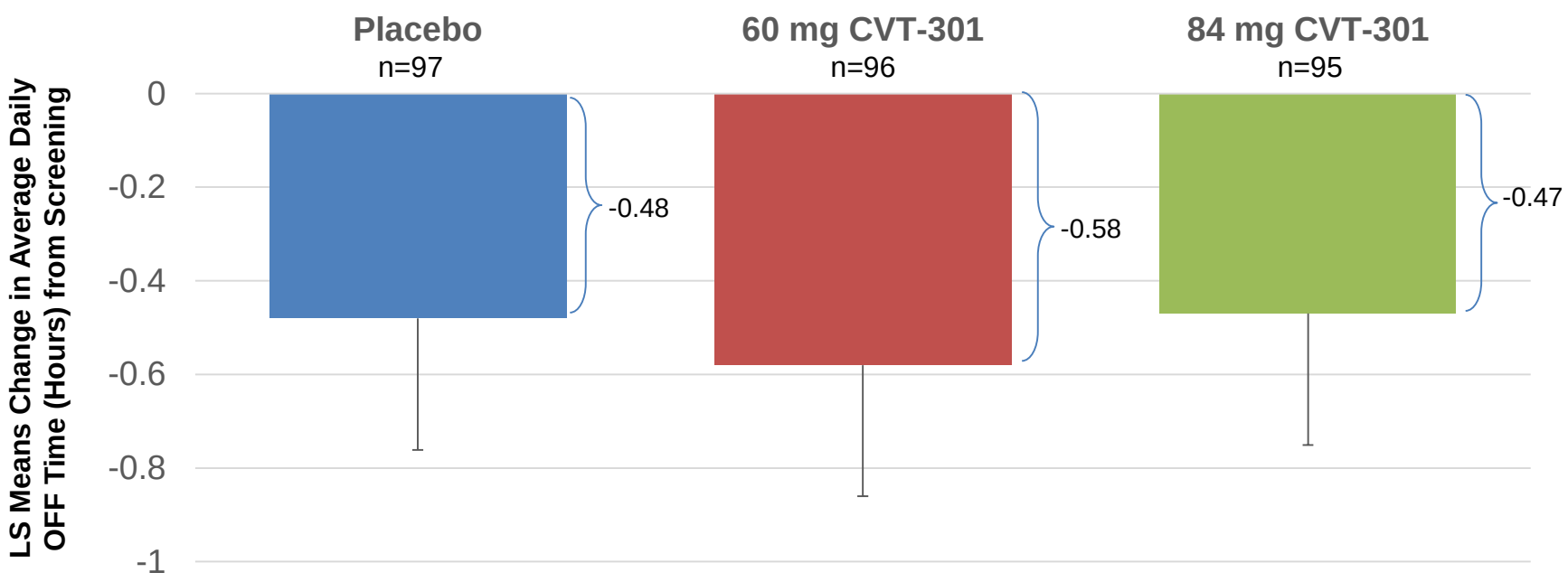
- **Patient global impression of change (PGI-C) at Week 12 consistent with effect on UPDRS3**
- **84 mg arm patients experiencing "improvement" or "much improvement" more than double that of placebo**
- **Improvement correlated with dose**

Nominal P-values: * p < 0.05, ** p< 0.01, *** p < 0.001

Note: PGI-C: Nominal p-values represent significance for any improvement in PGI-C over placebo, assuming worst case imputation for missing data if visit occurred

CVT-301-004
Secondary Endpoints: OFF Time at Week 12

Average Daily OFF Time Change from Screening

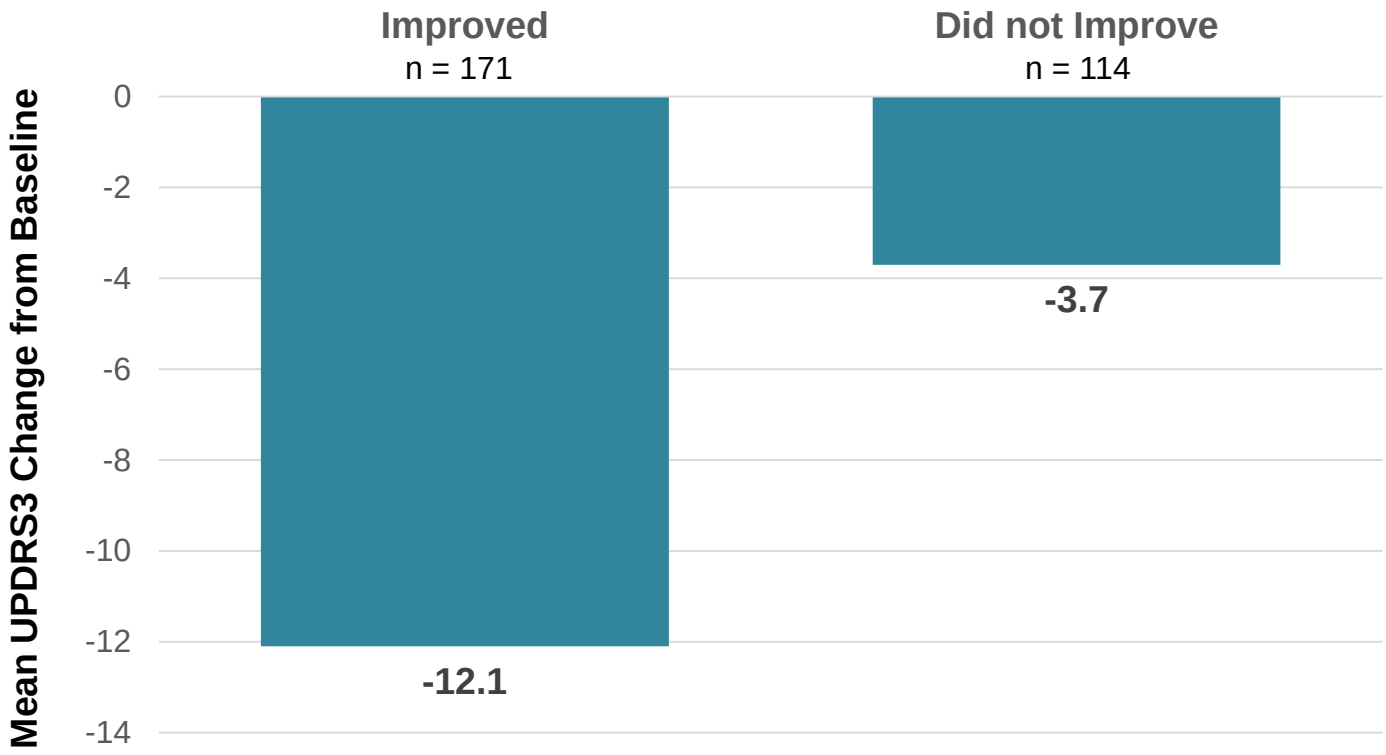


Significant OFF time improvement vs. placebo was not observed in CVT-301-004

Note: Error bars indicate standard errors

Post-hoc Analysis - PGI-C Improvement vs. UPDRS 3 Results

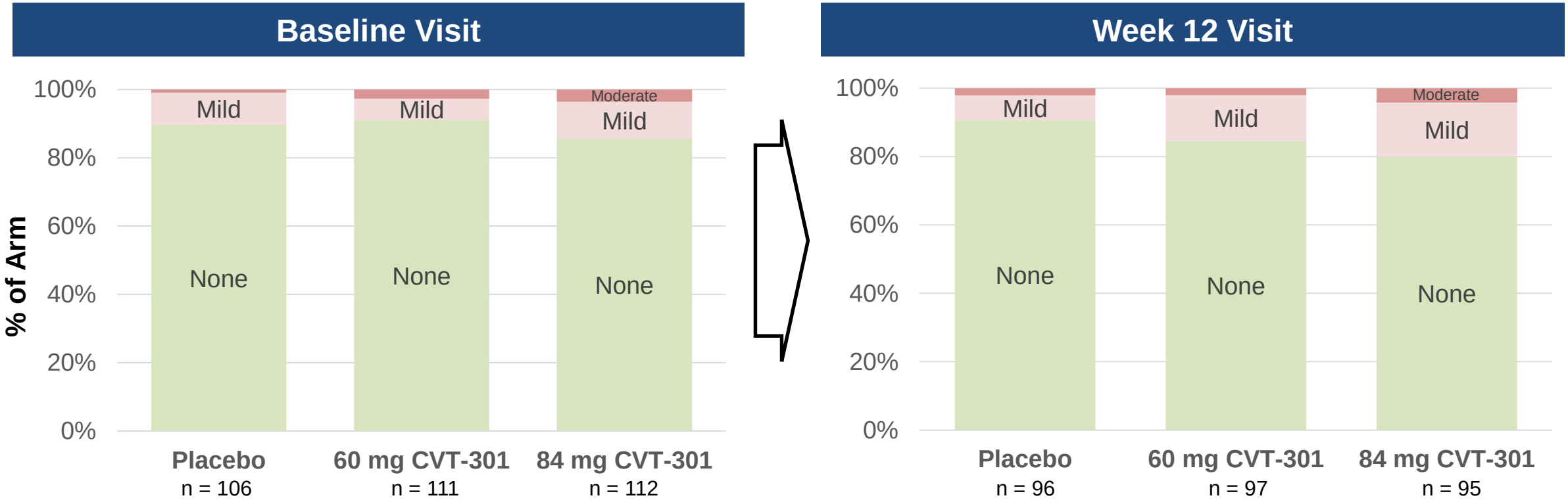
Changes in UPDRS 3 at 30 minutes in Patients that Did Improve vs. Patients that Did Not Improve in PGI-C (Week 12, Pooled* Patients)



* Pooled includes both arms of CVT-301 and placebo

Note: Post-hoc analysis is hypothesis generating

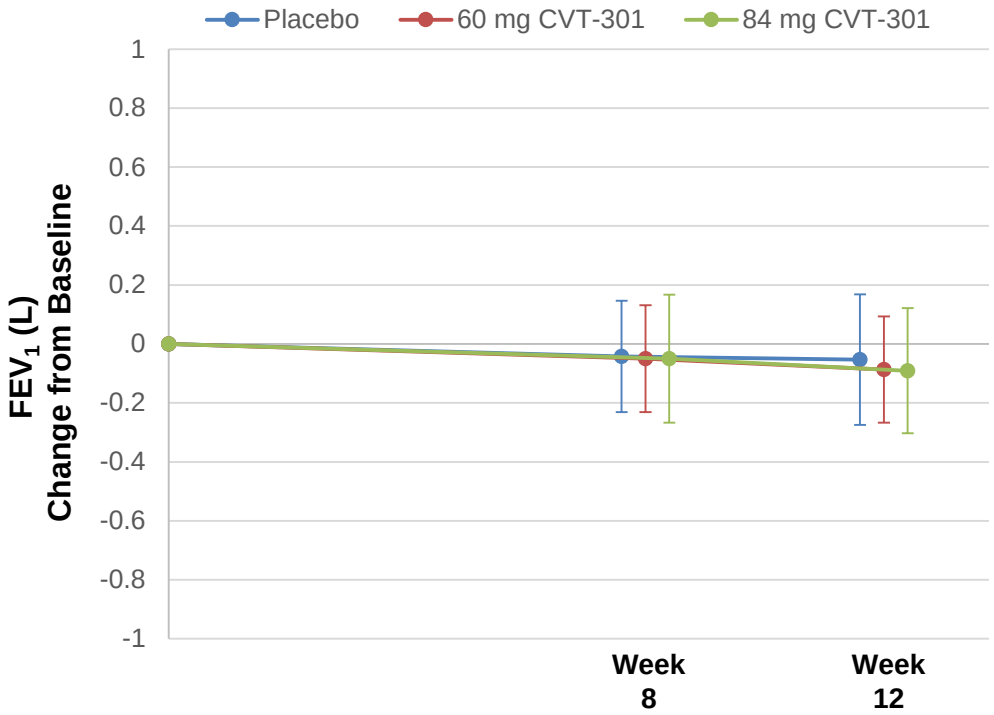
CVT-301-004
Dyskinesia Reported within 60 min CVT-301 Post-Inhalation (3 mo. Visit)



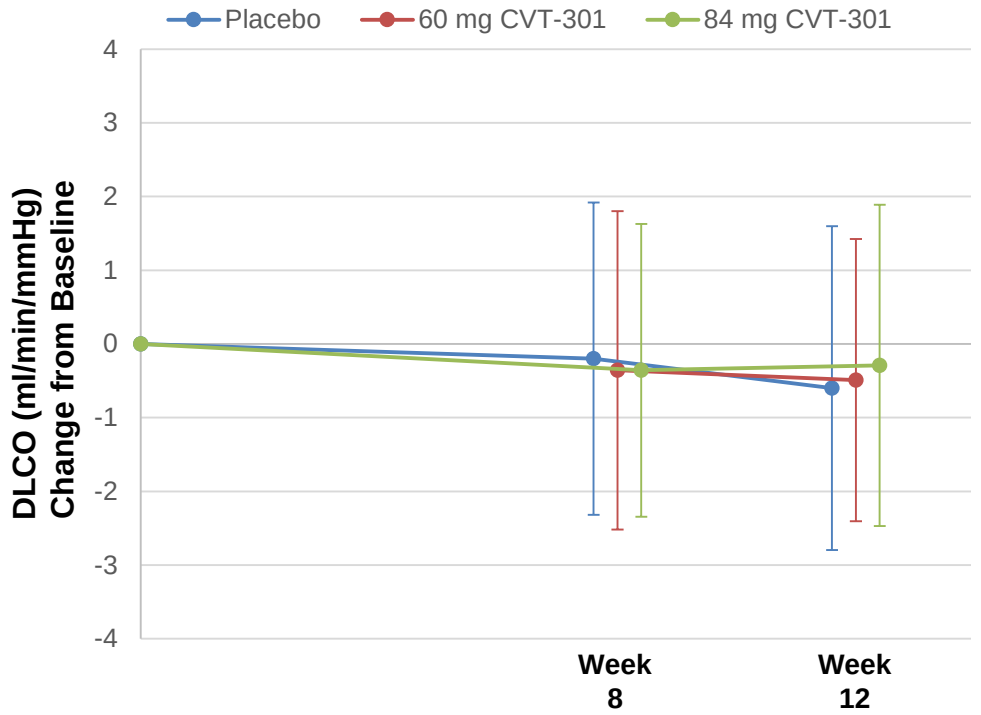
Most CVT-301 patients reported no dyskinesia: dyskinesia observed was mostly mild

CVT-301-004
Pulmonary Function Tests: FEV_1 & DLCO Change From Baseline

FEV_1



DLCO



Over the course of 3 months, there were no statistically significant differences for CVT-301 vs placebo on either FEV_1 or DLCO

Notes: Time points staggered for readability
Error bars represent standard deviations

CVT-301-004
Safety: Treatment Emergent Adverse Events

Preferred Term, n (%)	Placebo (n=112)	60 mg (n=113)	84 mg (n=114)
Cough	2 (1.8%)	17 (15.0%)	17 (14.9%)
Upper Resp Infection	3 (2.7%)	2 (1.8%)	7 (6.1%)
Nausea	3 (2.7%)	0	6 (5.3%)
Sputum discoloured	0	0	6 (5.3%)
Dyskinesia	0	5 (4.4%)	4 (3.5%)
Fall	2 (1.8%)	5 (4.4%)	3 (2.6%)
Nasopharyngitis	2 (1.8%)	2 (1.8%)	3 (2.6%)
Hallucination	2 (1.8%)	2 (1.8%)	2 (1.8%)
Headache	0	4 (3.5%)	2 (1.8%)
Pain in extremity	1 (0.9%)	2 (1.8%)	2 (1.8%)
Throat irritation	0	8 (7.1%)	1 (0.9%)
Dizziness	5 (4.5%)	2 (1.8%)	1 (0.9%)
Back pain	0	4 (3.5%)	1 (0.9%)
Influenza	0	4 (3.5%)	1 (0.9%)
Depression	2 (1.8%)	1 (0.9%)	1 (0.9%)
Hypertension	1 (0.9%)	2 (1.8%)	1 (0.9%)

- **Cough was most common AE for CVT-301**
  - Withdrawal due to cough < 2%
  - Most patients reported a single case in the pooled CVT-301 population
  - Majority of cough was mild
- **CVT-301 rates of AEs commonly seen with dopaminergic therapies:**
  - Nausea < 6%
  - Somnolence < 1%
  - Hypotension < 1%

Treatment emergent adverse events relative to screening visit

CVT-301-004 Summary

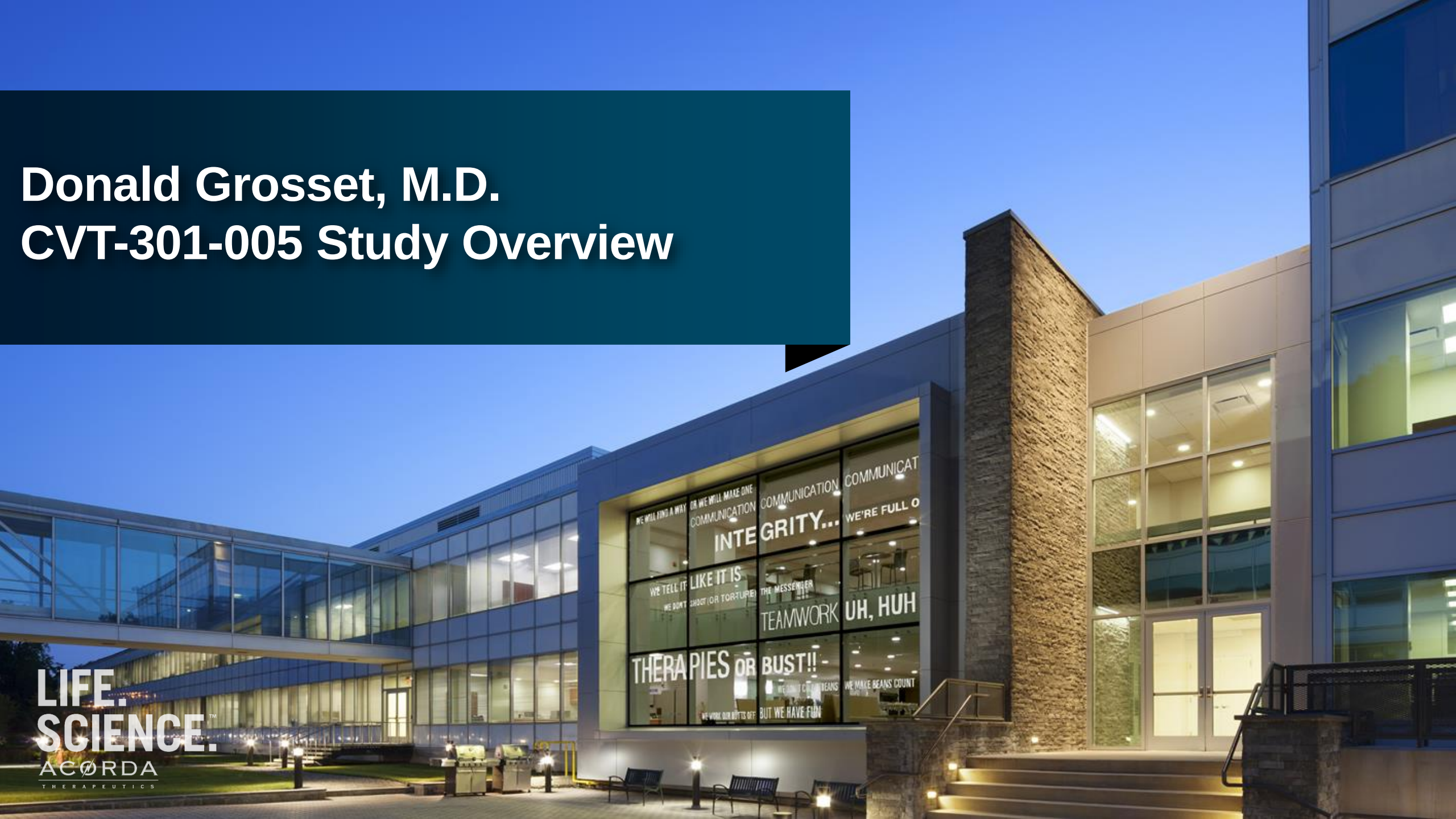
- **Study met primary endpoint at 30 minutes**
  - Clinically meaningful* change in UPDRS3 at 30 minutes relative to placebo sustained through 60 minutes
  - Nominally statistically significant at 10 minutes (84 mg dose)
  - Trend (p=0.062) towards improvement at 20 minutes (84 mg dose)

- **Additional secondary endpoints were supportive of primary endpoint result**
  - Statistically significant improvement in ON at 60 minutes (84 mg dose)
  - PGI-C showed nominal significance
  - Diary-recorded OFF time did not show any significant differences

- **Safety profile**
  - 1.3% withdrawal rate due to cough, the most common adverse event
  - Adverse events were mostly mild
  - Mild to no dyskinesia in over 95% of patients in-clinic
  - Discontinuation rates due to adverse events < 6%

* Shulman, LM et al. The Clinically Important Difference on the Unified Parkinson's Disease Rating Scale. Arch Neurol 67, 64-70 (2010).

Donald Grosset, M.D.
CVT-301-005 Study Overview



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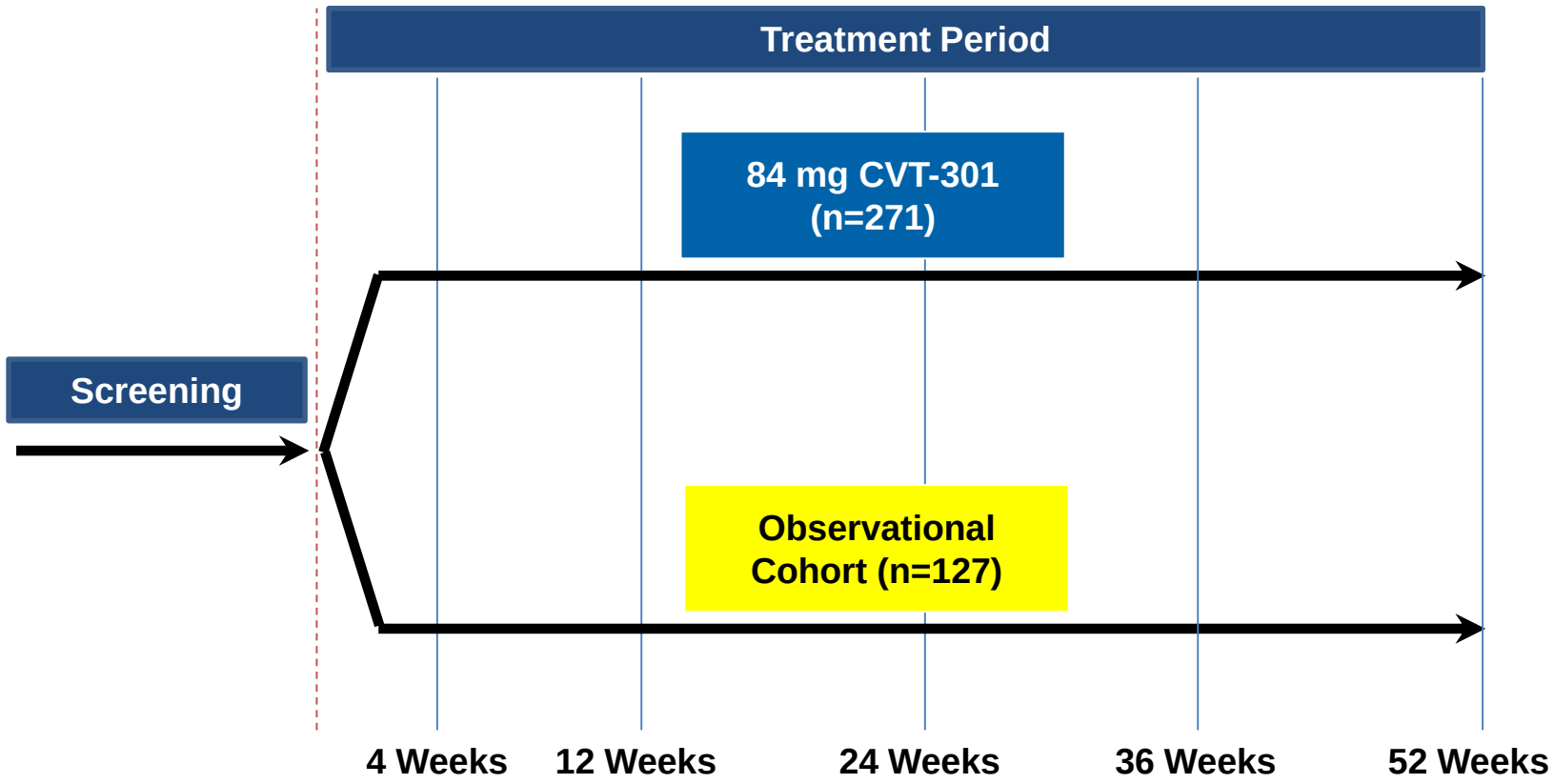
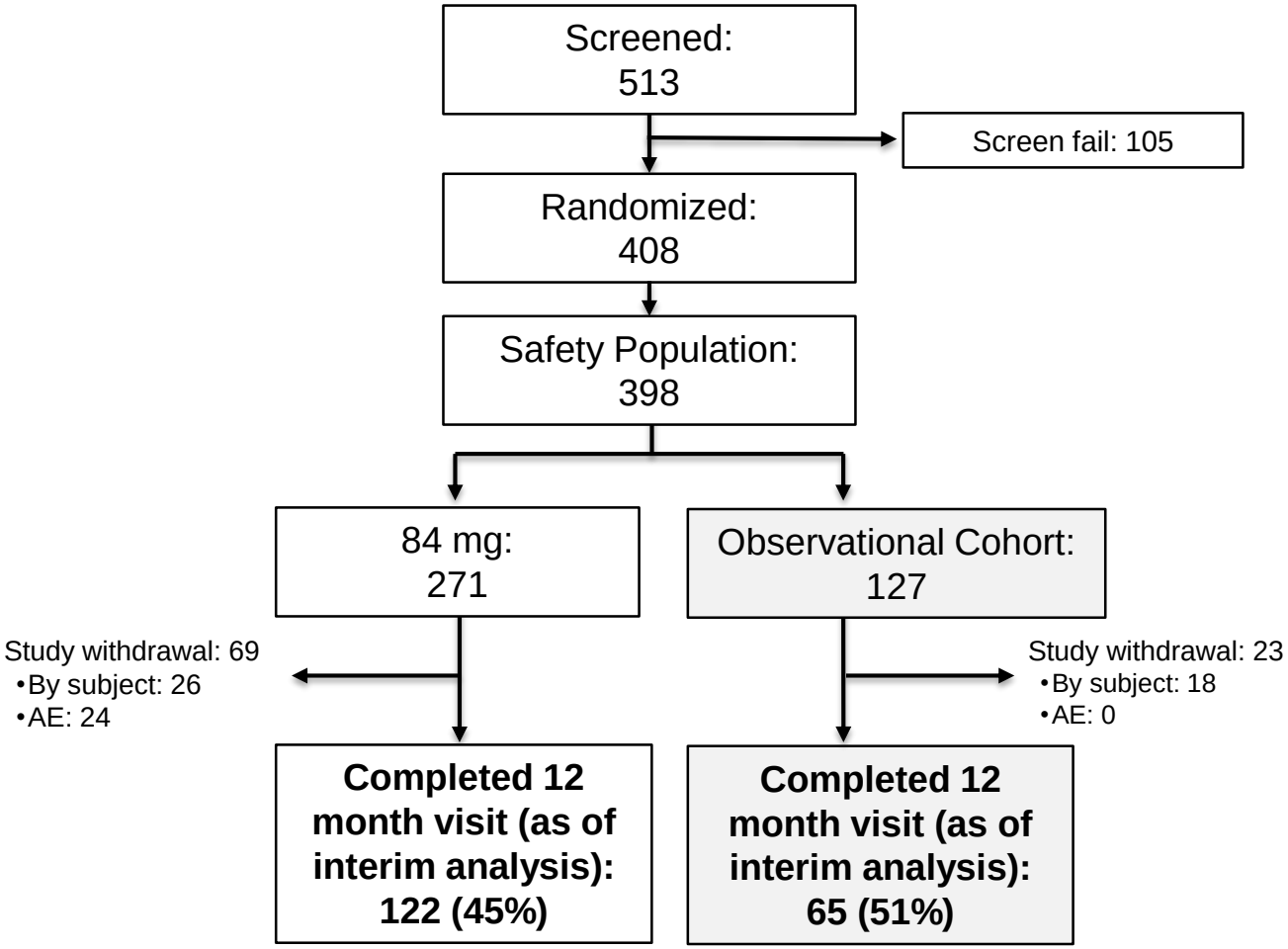
CVT-301-005 Study Design



- **CVT-301-005 was a safety study comparing treatment with CVT-301 (84 mg) to an observational control group of PD patients**
  - Observational cohort allows for the comparison to pulmonary function in PD patients (which may decline over time)
- **Primary objective was on pulmonary safety out to a year of treatment vs. observational cohort**
- **Exploratory efficacy conducted for most endpoints in the active treatment arm only**

CVT-301-005 Patient Disposition



- **7.4% of the CVT-301 cohort withdrew due to a treatment-emergent adverse event**
- **3 patients withdrew due to cough (1.1%)**
- **No other AE resulting in withdrawal represented > 1% of the studied population**

Note: As of interim analysis, >99% of patients completed 9 month visit.

CVT-301-005 Baseline Characteristics

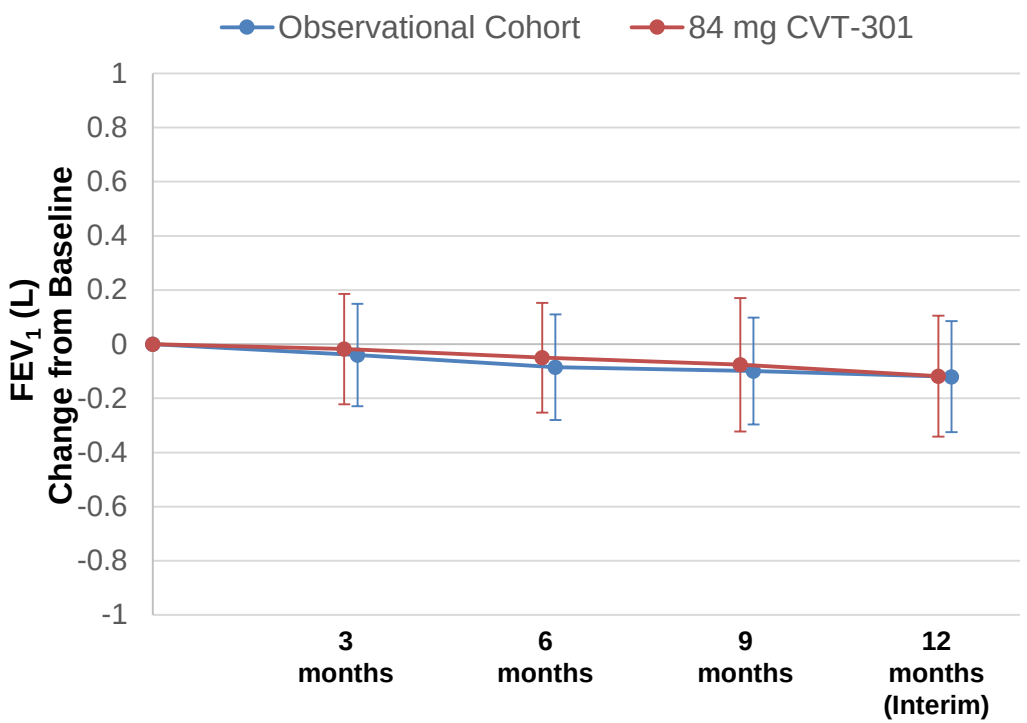
		CVT-301-005	
		Observational Cohort	CVT-301 84 mg
Parkinson's Disease Characteristics	Mean age (yrs)	64.2	63.6
	Sex (male), %	61.4%	59.4%
	H&Y ≥2.5 (More Severe)	53%	53%
	Duration of PD (yrs)	9.7 years	9.0 years
	CD/LD treatment (yrs)	7.3 years	7.2 years
	Daily Levodopa (mg)	874.1	777.2
	CD/LD (doses)	5.2	5.1
	Daily OFF Periods incl. AM	3.7	3.6
	Daily OFF incl. AM (hrs)	5.7	5.6

CVT-301-005 Safety Overview

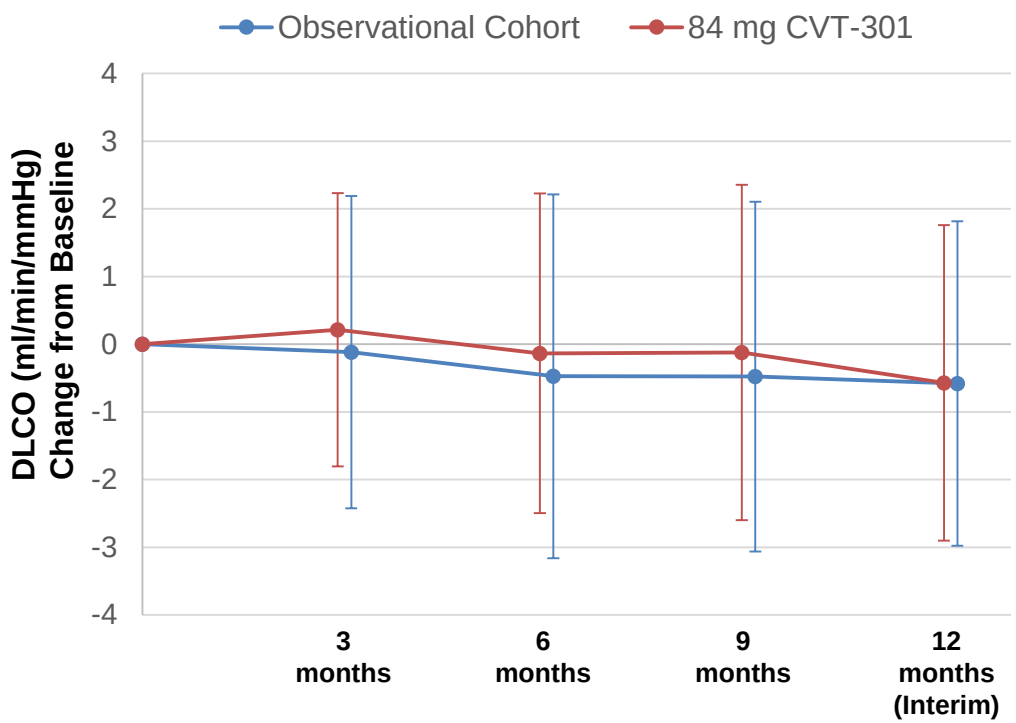
- **Pulmonary function tests were conducted to characterize CVT-301's effects on lung function compared to the natural course of disease, using commonly used lung function measures:**
  - FEV1: forced expiratory volume in 1 second
  - DLCO: diffusing capacity of the lung for carbon monoxide
- **Adverse events were also recorded for this long term study**
  - CVT-301-005 design included an observational (non-interventional) control, allowing for the monitoring of adverse events out to 1 year

CVT-301-005
Pulmonary Function Tests: FEV_1 & DLCO Change From Baseline

FEV_1



DLCO



No statistical difference between CVT-301 and observational cohort in FEV1 or DLCO in CVT-301-005

Notes: Time points staggered for readability
Error bars represent standard deviations

CVT-301-005
Safety: Treatment Emergent Adverse Events

Preferred Term, n (%)	Obser Cohort (n=127)	CVT-301 (n=271)
Cough	1 (0.8%)	35 (12.9%)
Nasopharyngitis	6 (4.7%)	17 (6.3%)
Dyskinesia	4 (3.1%)	15 (5.5%)
Fall	3 (2.4%)	14 (5.2%)
Back pain	4 (3.1%)	12 (4.4%)
Upper respiratory tract infection	3 (2.4%)	12 (4.4%)
Nausea	1 (0.8%)	10 (3.7%)
Hypertension	3 (2.4%)	9 (3.3%)
Sputum discolored	0	9 (3.3%)
Throat irritation	0	9 (3.3%)
Arthralgia	2 (1.6%)	8 (3.0%)
Orthostatic Hypotension	3 (2.4%)	7 (2.6%)
Headache	1 (0.8%)	7 (2.6%)
Parkinson's disease	4 (3.1%)	6 (2.2%)
UTI	2 (1.6%)	6 (2.2%)
Dizziness	1 (0.8%)	6 (2.2%)
Depression	2 (1.6%)	5 (1.8%)
Bronchitis	4 (3.1%)	5 (1.8%)
Insomnia	5 (3.9%)	3 (1.1%)
Musculoskeletal pain	4 (3.1%)	2 (0.7%)
Somnolence	1 (0.8%)	0

- **Most commonly observed AE was cough**
  - Majority of cases (> 90%) were characterized as mild
- **CVT-301 rates of AEs commonly seen with dopaminergic therapies:**
  - Nausea (3.7%)
  - Orthostatic hypotension (2.6%)
  - Somnolence (0%)
- **SAEs reported in 14.9% of patients in the CVT-301 arm versus 10.2% in the observational control**
  - UTI most common (1.4%)
  - No other SAEs in the CVT-301 arm observed at >1%

CVT-301-005 Safety Study Summary

- **Pulmonary function was not statistically different from observational cohort out to 12 months using standard lung function measures (FEV1, DLCO) as of the interim analysis**

- **Cough was the most common adverse event**
  - Occurred in 12.9% of CVT-301 84 mg vs. < 1% in the observational control
  - Majority of cases (> 90%) were characterized as mild
  - All other AEs occurred at less than 7% of patients

- **Discontinuation due to AE was 7.4%**

- **Dopaminergic side effect* rates were each < 6% during the study**
  - Includes dyskinesia

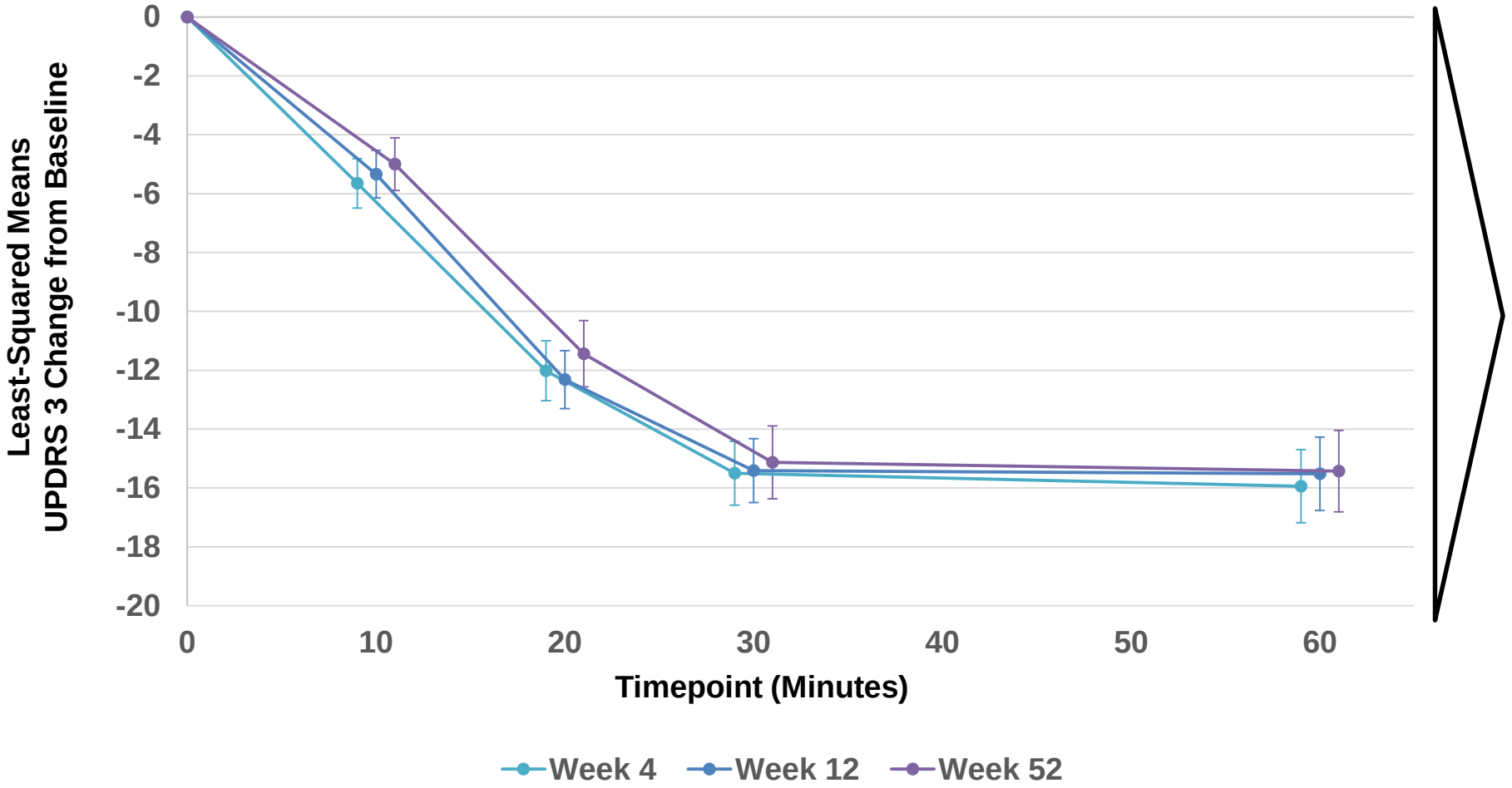
* Examples include nausea, orthostatic hypotension, somnolence

CVT-301-005 Exploratory Efficacy Measures

- **Uncontrolled exploratory efficacy measurements* (only conducted in the CVT-301 arm) also measured in CVT-301-004:**
  - UPDRS3
  - Responder ON
  - PGI-C
  - OFF time

* Exploratory analyses are hypothesis generating

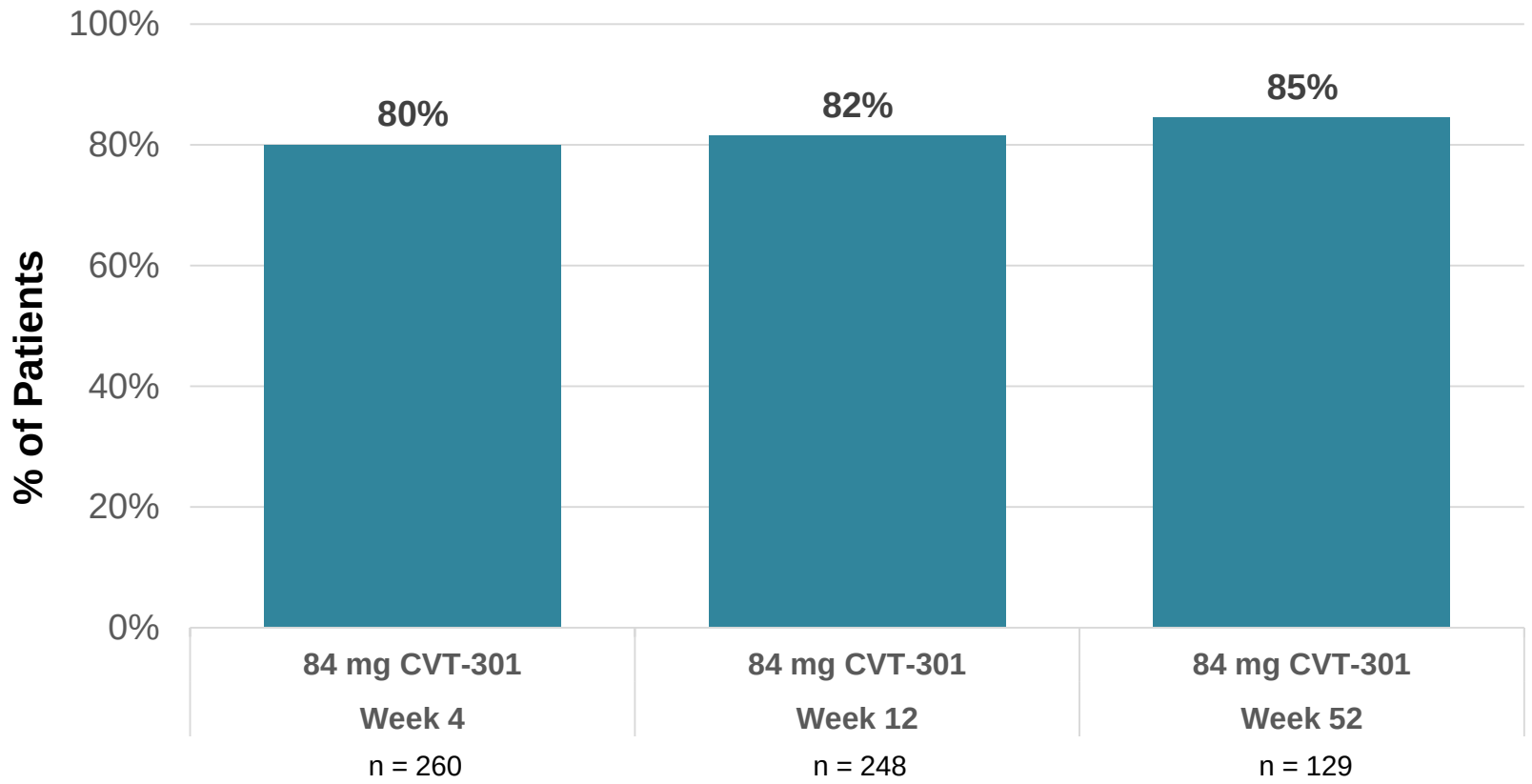
CVT-301-005 Exploratory Efficacy
UPDRS3 Change from Baseline Through 52 Weeks



CVT-301-005 open label UPDRS3 change at 52 weeks largely stable as compared to week 4 and week 12 data

Notes: Time points staggered for readability
Error bars indicate standard errors

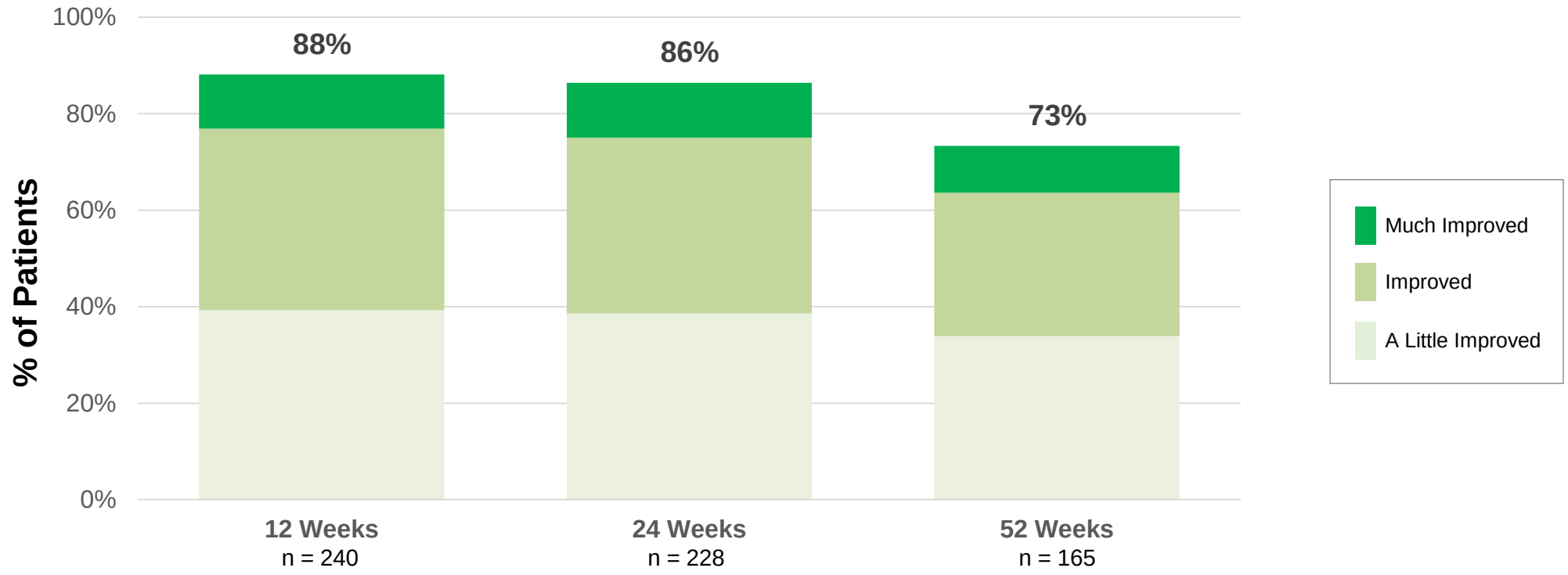
CVT-301-005 Exploratory Efficacy
Responder % ON at 60 minutes



Percentage of patients ON at 60 minutes remained at similar levels through 52 weeks

Note: Assumes worst case imputation for missing data if visit occurred

CVT-301-005 Exploratory Efficacy
PGI-C: Improvement

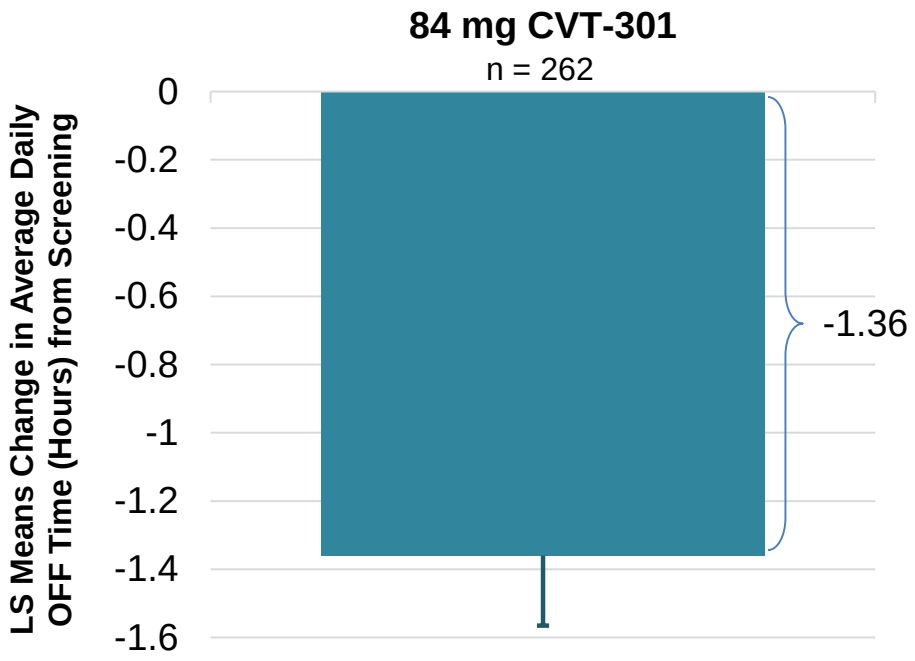


Patient global impression of improvement remains greater than 70% of patients at month 12 and greater than 80% at the 6 month visit

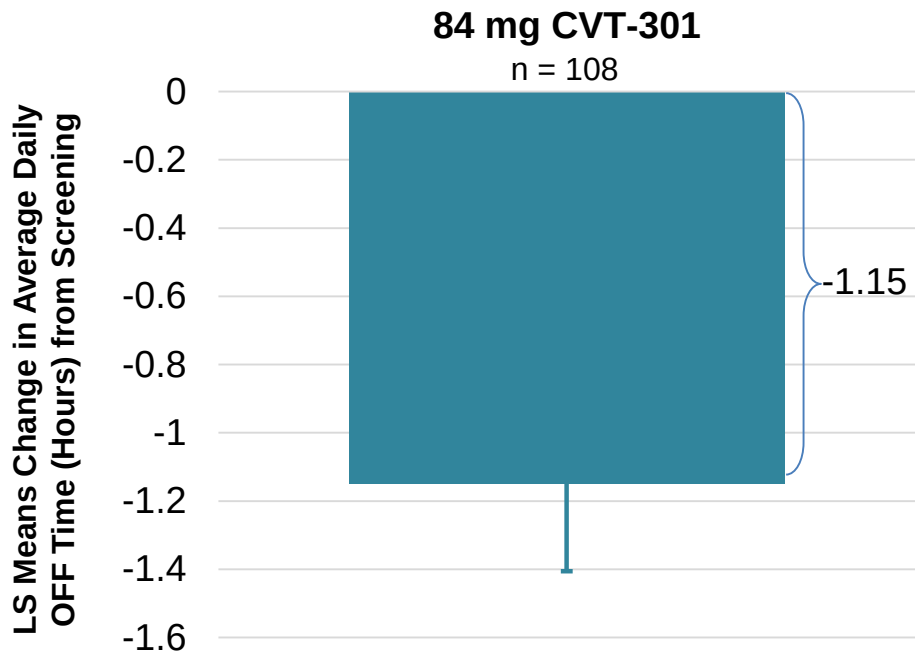
Note: Assumes worst case imputation for missing data if visit occurred; early terminations pooled to the last visit

CVT-301-005 Exploratory Efficacy
OFF Time Reduction at Week 4 and Week 52

Week 4 Visit



Week 52 Visit (Interim Analysis)



Exploratory OFF time data (open label) showed changes in OFF time of 1.15-1.36 hours from baseline

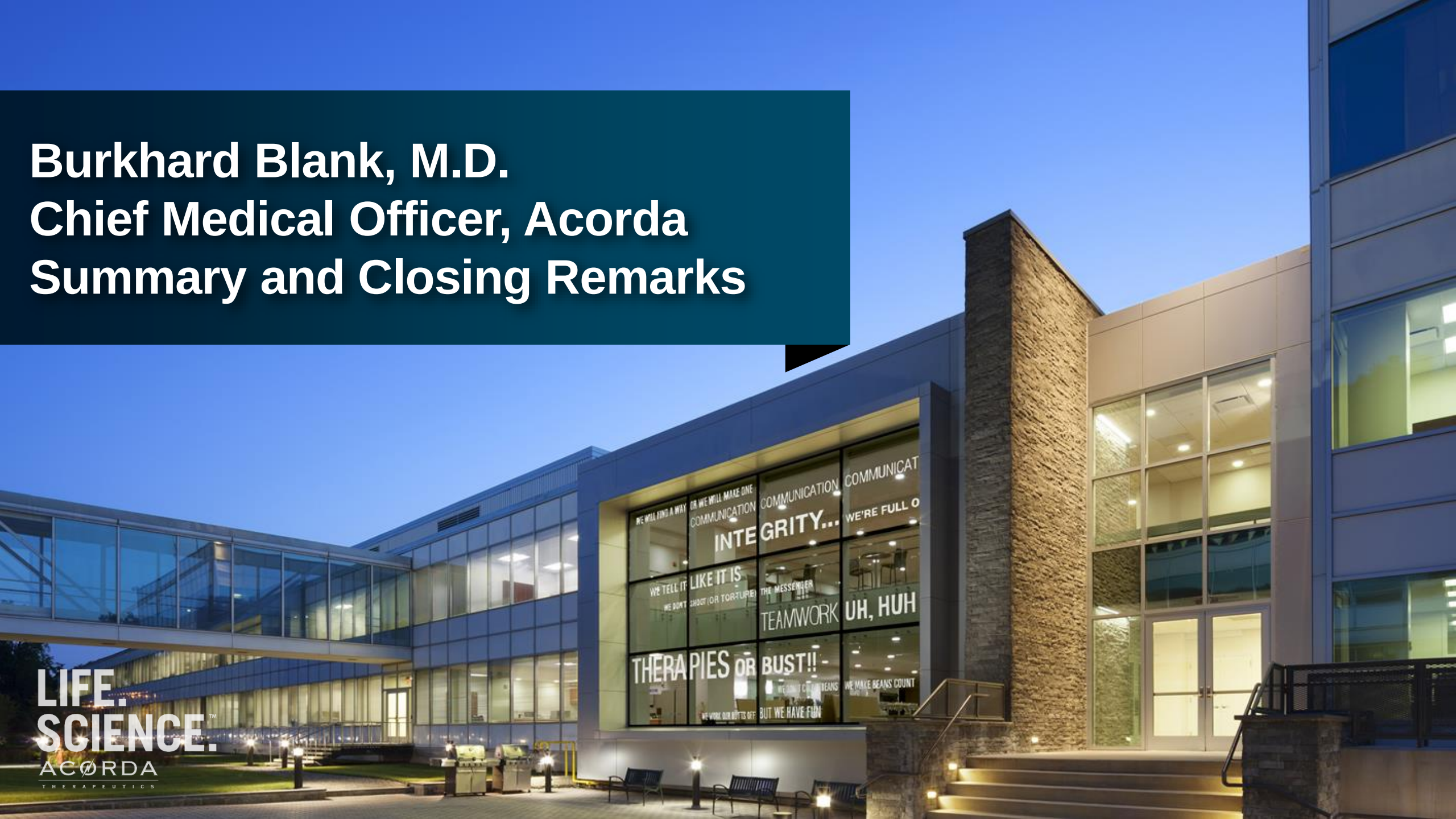
Note: Error bars represent standard errors

CVT-301-005 – Summary

- **No statistically significant differences in lung function tests (FEV_1, DLCO) observed for CVT-301 84 mg versus observational control out to 1 year***
- **Adverse events were mostly mild, with cough being the most common AE (12.9%)**
  – Withdrawals due to cough occurred in three patients (1.1%)
- **Over 12 months, exploratory efficacy supportive of results from CVT-301-004**

* As of interim analysis

Burkhard Blank, M.D.
Chief Medical Officer, Acorda
Summary and Closing Remarks



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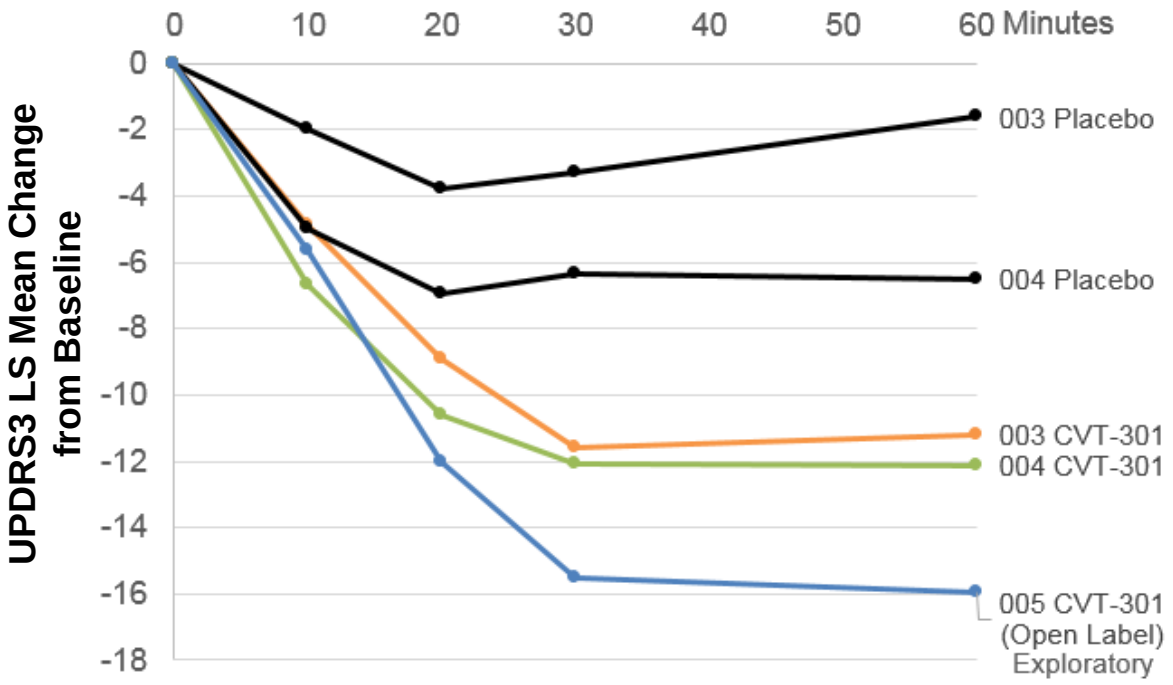
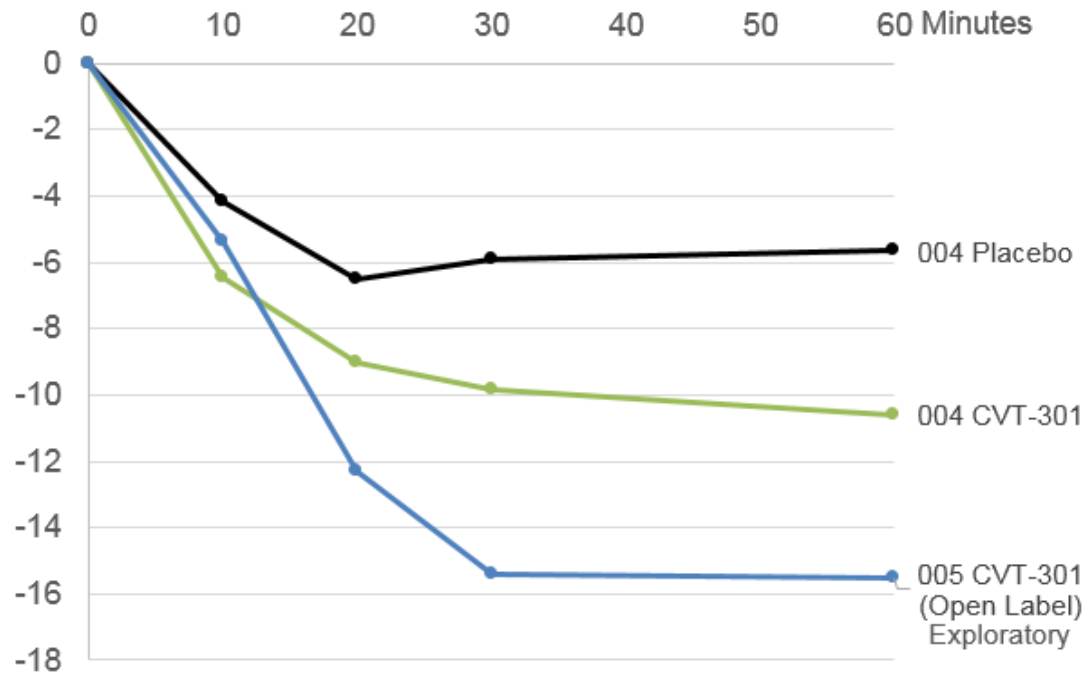
Efficacy Data over Time
UPDRS3 Change from Baseline (Studies 003, 004 and 005)

4 Week Visit
(CVT-301 82.8/84 mg dose shown)



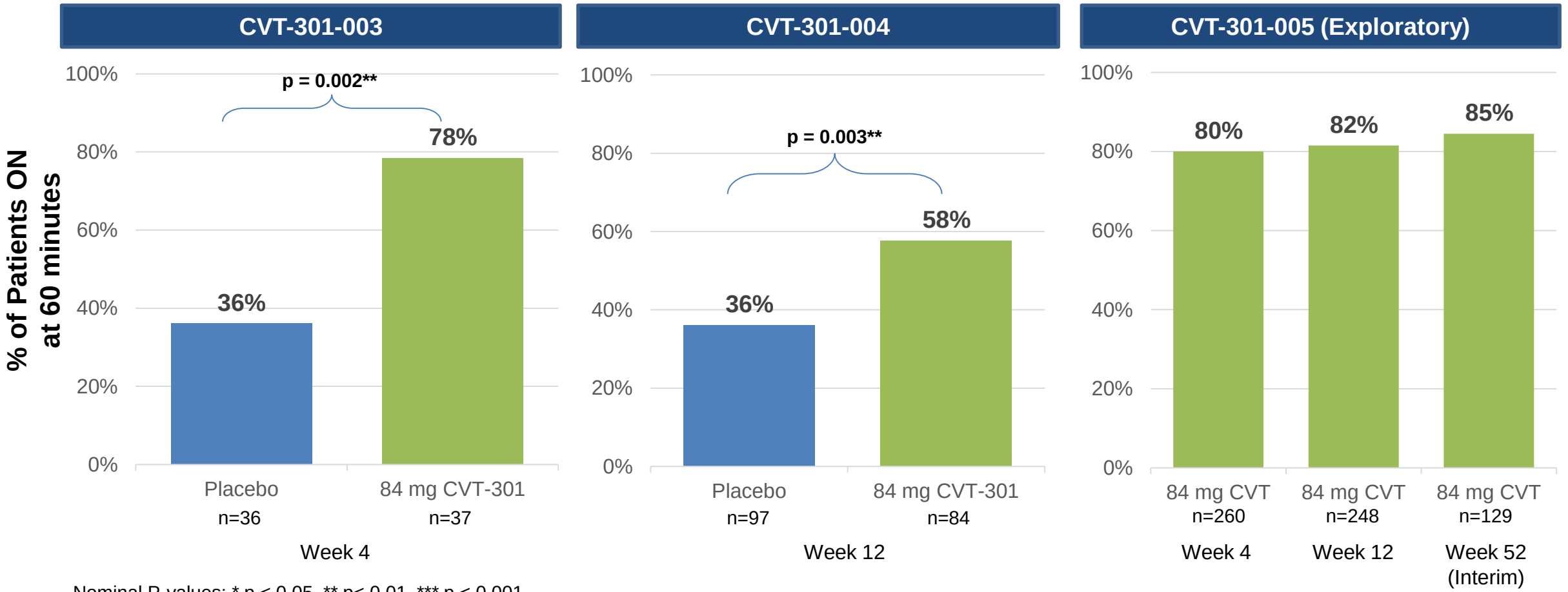
12 Week Visit
(CVT-301 82.8/84 mg dose shown)



Notes: Intention to Treat population, LS means

Formulation in 003 high dose used lower fill weight (82.8 mg) as compared to comparable dose in studies 004 or 005 (84 mg); both formulations reflect 50 mg equivalent fine particle doses

CVT-301 Showed Greater Responder ON % Across All Studies

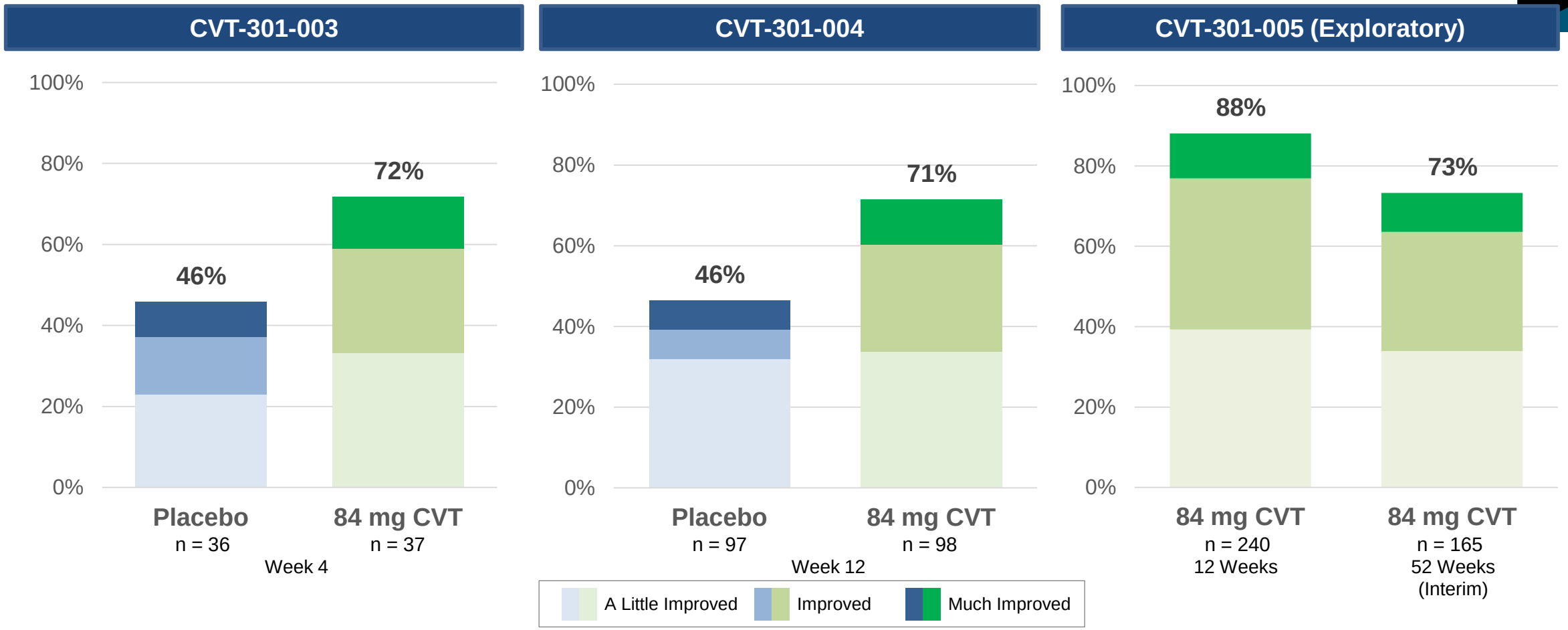


Nominal P-values: * p < 0.05, ** p< 0.01, *** p < 0.001

Notes: Assumes worst case imputation for missing data if visit occurred for 004 and 005

Formulation in 003 high dose used lower fill weight (82.5 mg) as compared to comparable dose in studies 004 or 005 (84 mg); both formulations reflect 50 mg equivalent fine particle doses

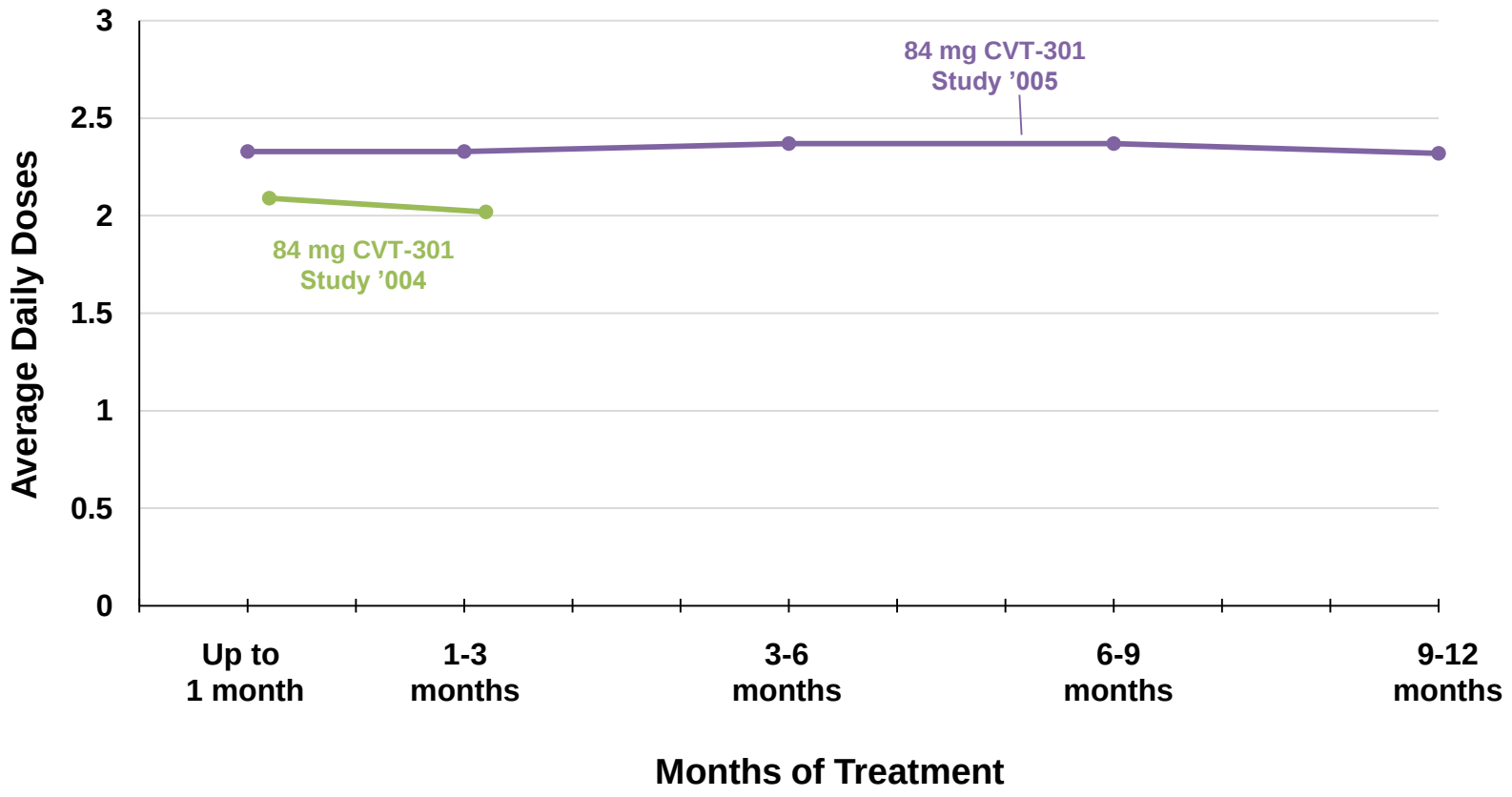
PGI-C (Improvement) Across Studies



Consistency in improved and much improved patients across the CVT-301 program

Note: Formulation in 003 high dose used lower fill weight (82.5 mg) as compared to comparable dose in studies 004 or 005 (84 mg); both formulations reflect 50 mg equivalent fine particle doses; early terminations pooled to the last visit

CVT-301 Average Usage through Last Study Visit



- **CVT-301 averaged 2.3 doses / day in year-long study and 2.0 doses / day over three months**
- **Total capsules self-administered by patients during treatment:**
  - Study 004: 86,295 (3 months)
  - Study 005: 385,175 (12 months)

CVT-301 Phase 3 Program Overall Summary

- **CVT-301 has been studied in over 1000 subjects in multiple clinical trial settings encompassing over 15 countries across the US and EU**

- **CVT-301's Study 004 had statistically significant improvements in UPDRS3 at 30 minutes versus placebo with supportive secondary endpoint results at the 84 mg dose:**
  - Responder ON at 60 minutes was statistically significant
  - UPDRS3 nominally statistically significant at 10 minutes and 60 minutes with trends observed at 20 minutes
  - PGI-C nominally statistically significant – most of difference vs. placebo in "Improved" and "Much improved" categories

- **CVT-301-005 exploratory efficacy also supportive**

- **Safety profile was consistent across CVT-301-004 and CVT-301-005**
  - No statistically significant differences in acute and chronic pulmonary safety as measured by FEV1 or DLCO
  - Cough was the most common AE
  - No concerning dopaminergic AEs