

Characterization of Puff Topography of Adult Conventional Cigarette Smokers and Exclusive e-Vapor Users During Ad Libitum use of MarkTen® e-Vapor Products

*Jeff Edmiston, Andrea Vansickel, Qiwei
Liang, Maria Gogova, Mohamadi
Sarkar, George Karles*



Altria

Altria Client Services

Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems

DRAFT GUIDANCE – May 2016

“Assessment of user topography (how individual users consume the product, e.g., the number of puffs, puff duration, puff intensity, duration of use), the frequency with which consumers use the product, and the trends by which users consume the product over time;”

E-Vapor Products (all unbranded)

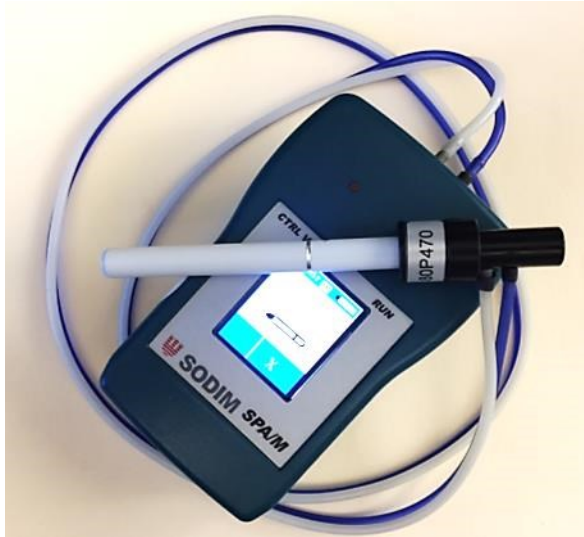
Group 1: Non-Menthol Test Products

- **Bold Classic:** XL40CB [4.0% nicotine by weight]
- **Fusion:** XL25F [2.5% nicotine by weight]
- **Classic:** XL35C [3.5% nicotine by weight]

Group 2: Menthol Test Products

- **Bold Menthol:** XL40MB [4.0% nicotine by weight]
- **Winter Mint:** XL35WM [3.5% nicotine by weight]
- **Menthol:** XL35M [3.5% nicotine by weight]

SODIM Puff Analyzer Mobile



- 3 pressure sensors (two measure differences at mouthpiece, 1 atmospheric)
- 50 millisecond recording
- Analyzed with SODafc software

Study Purpose

To characterize the puff topography (puff count, puff duration, puff volume) when using MarkTen[®] XL in:

- **Adult cigarette smokers on Day 1 and after 1 week of use**
 - No e-vapor products in the past 30 days
- **Adult e-vapor users on Day 1 and after 1 week of use**
 - Minimum of 6 months and exclusively for a minimum of the past 30 days

Study Conduct

N=121

61 Cigarette Smokers (CS)
60 e-Vapor Users (EV)

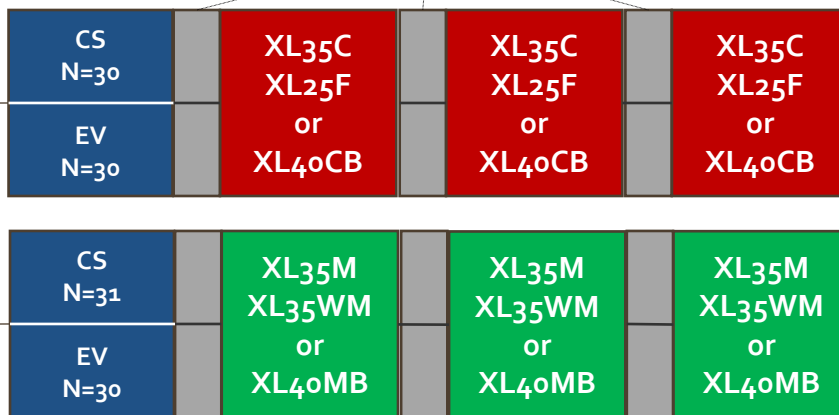
Eligibility
and Safety
Screening

Group 1

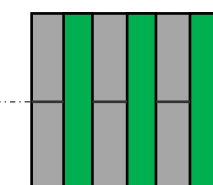
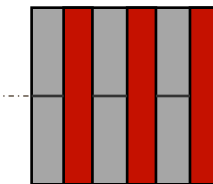
Group 2

Product
Trial
Group 1:
Non-
Menthol

Product
Trial
Group 2:
Menthol



1 week
with last
product
used on
Day 1



Day 8 (+/- 1 Day)

Visit 1:
Screening

Subjects self
selected:

- Non-menthol
- Menthol

Visit 2:

- Willing to use all three products after trial

Day 1: 90 min 90 min 90 min

Visit 3:

- Random assignment to use schedules
- 3 X 90 min use with SODIM SPA/M

Visit 4:
Day 8 repeated all Day
1 assessments

Group 1



Altria

Altria Client Services

Group 1: Study Participant Demographics

		Cigarette Smokers (N=30)	e-Vapor Users (N=30)	Total (N=60)
Age (years)	Mean	40.1	39.4	39.8
	SD	11.2	11.9	11.5
Sex	Male	13 43.3%	18 60.0%	31 51.7%
	Female	17 56.7%	12 40.0%	29 48.3%
Race	Black	16 53.3%	4 13.3%	20 33.3%
	White	11 36.7%	21 70.0%	32 53.3%
	Other	3 10.0%	5 16.7%	8 13.3%

Group 1: Tobacco Use History

Cigarette Smokers:

Years Smoking **15** (+/- 9)

Cigarettes Per Day **14.8** (+/-4.1)

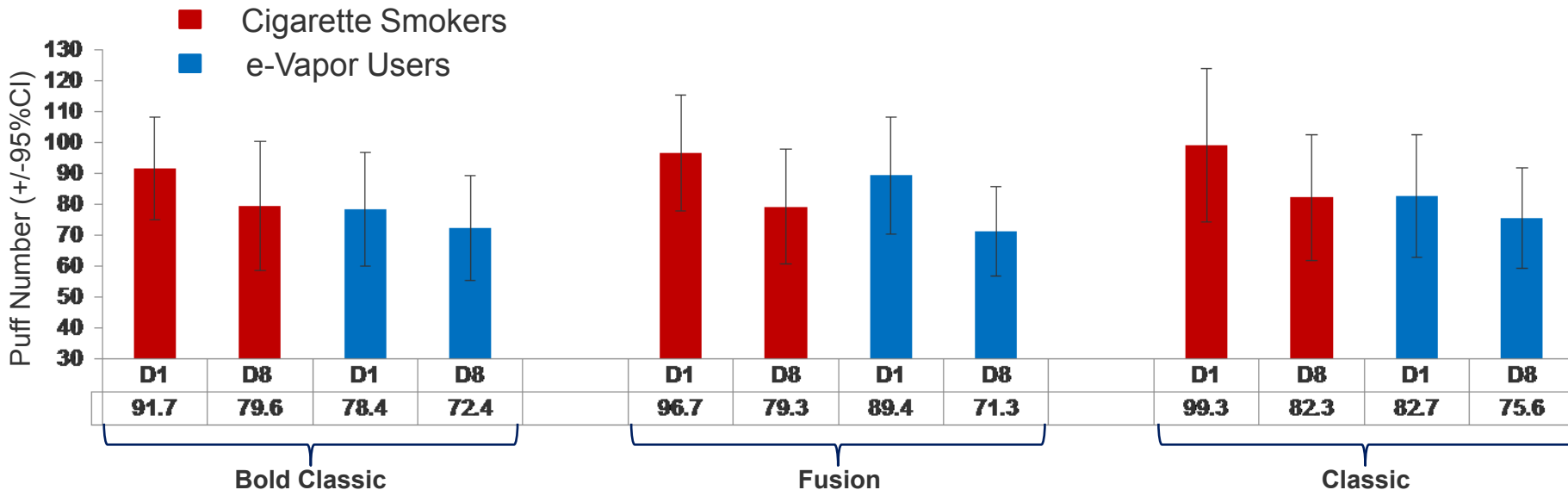
e-Vapor Users:

Years e-Vapor Use **1.9** (+/-1.6)

Type of e-Vapor:

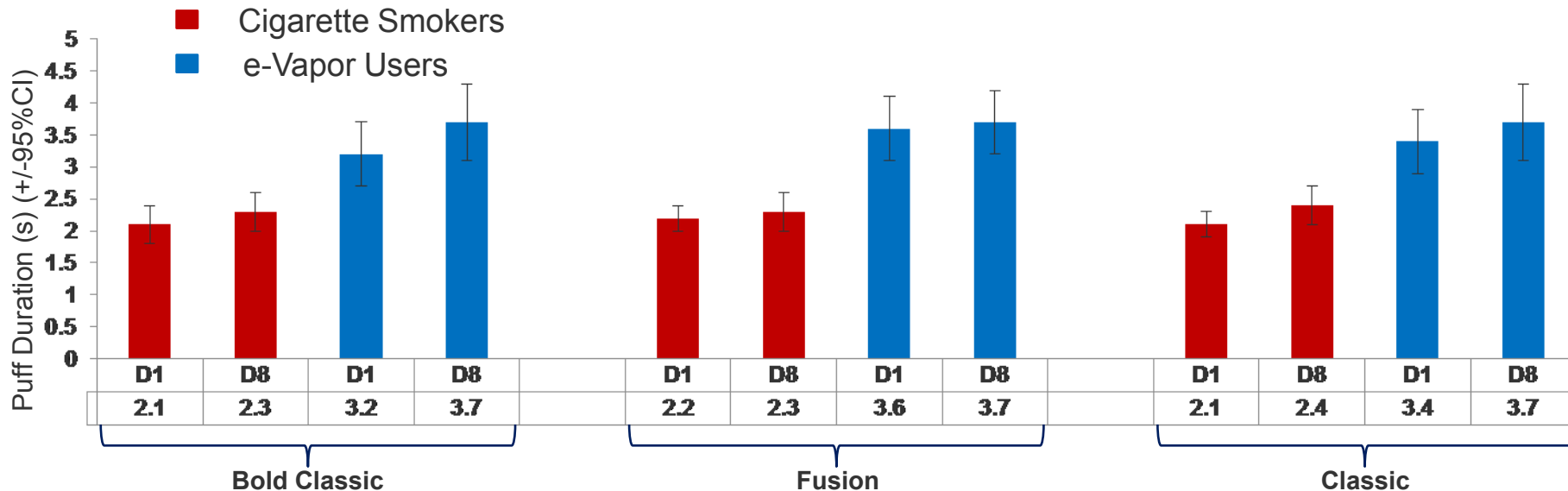
- **Disposable / Rechargeable** **8** (26.7%)
- **e-Liquid Refillable** **22** (73.3%)

Group 1: Average Puff Counts Over 90 Minutes



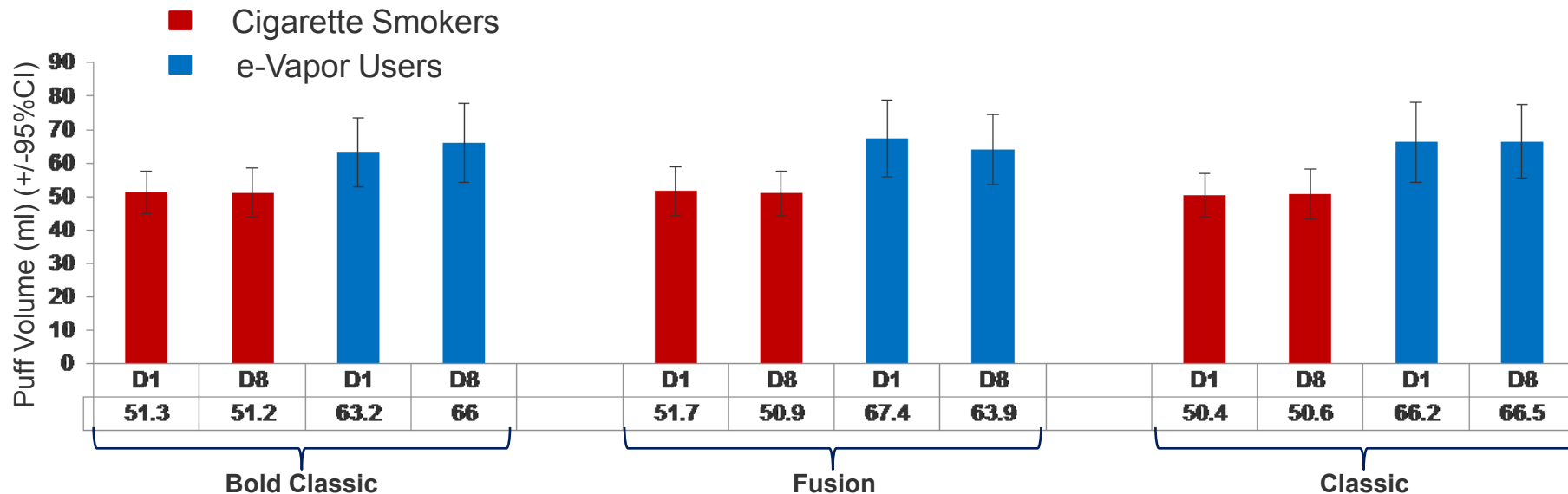
Effect	P value
Smokers vs. e-Vapor Users	0.6917
Day 1 vs. Day 8	<0.0001
Smokers or e-Vapor Users vs. Products	0.8565

Group 1: Average Puff Duration



Effect	P value
Smokers vs. e-Vapor Users	<0.0001
Day 1 vs. Day 8	<0.0001
Smokers or e-Vapor Users vs. Products	0.2954

Group 1: Average Puff Volume



Effect	P value
Smokers vs. e-Vapor Users	0.0727
Day 1 vs. Day 8	0.6004
Smokers or e-Vapor Users vs. Products	0.2910

Group 2



Altria

Altria Client Services

Group 2: Study Participant Demographics

		<u>Cigarette Smokers</u> (N=31)	<u>e-Vapor Users</u> (N=30)	<u>Total</u> (N=61)
Age (years)	Mean	37.8	40.4	39.1
	SD	11.5	12.4	12
Sex	Male	14 45.20%	18 60.00%	32 52.50%
	Female	17 54.80%	12 40.00%	29 47.50%
Race	Black	24 77.40%	17 56.70%	41 67.20%
	White	4 12.90%	12 40.00%	16 26.20%
	Other	3 9.70%	1 3.30%	4 6.60%

Group 2: Tobacco Use History

Cigarette Smokers:

Years Smoking **14.6** (+/- 11)

Cigarettes Per Day **13.6** (+/-4.7)

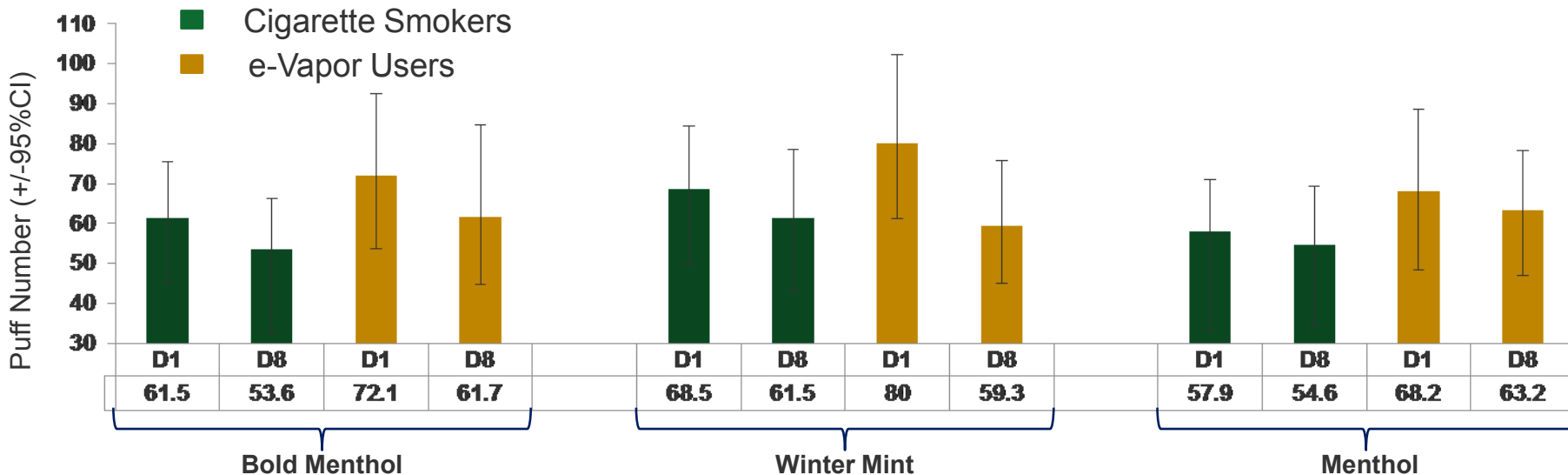
e-Vapor Users:

Years e-Vapor Use **2.2** (+/-2.1)

Type of e-Vapor:

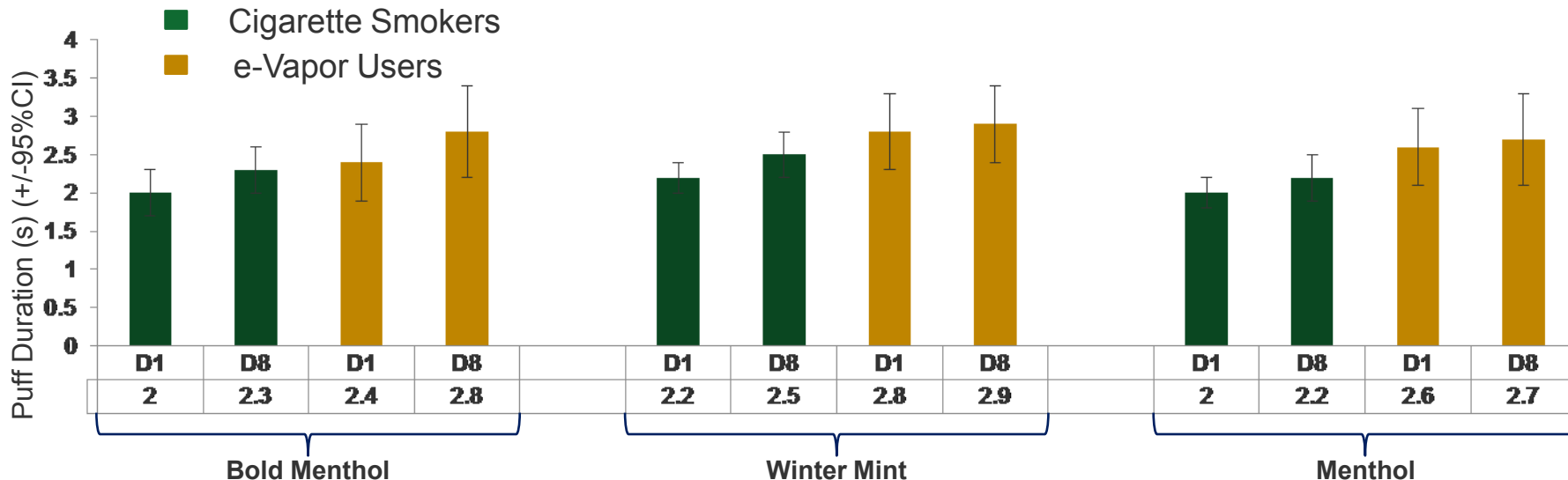
- **Disposable / Rechargeable** **9** (30.0%)
- **e-Liquid Refillable** **21*** (70.0%)

Group 2: Average Puff Counts Over 90 Minutes



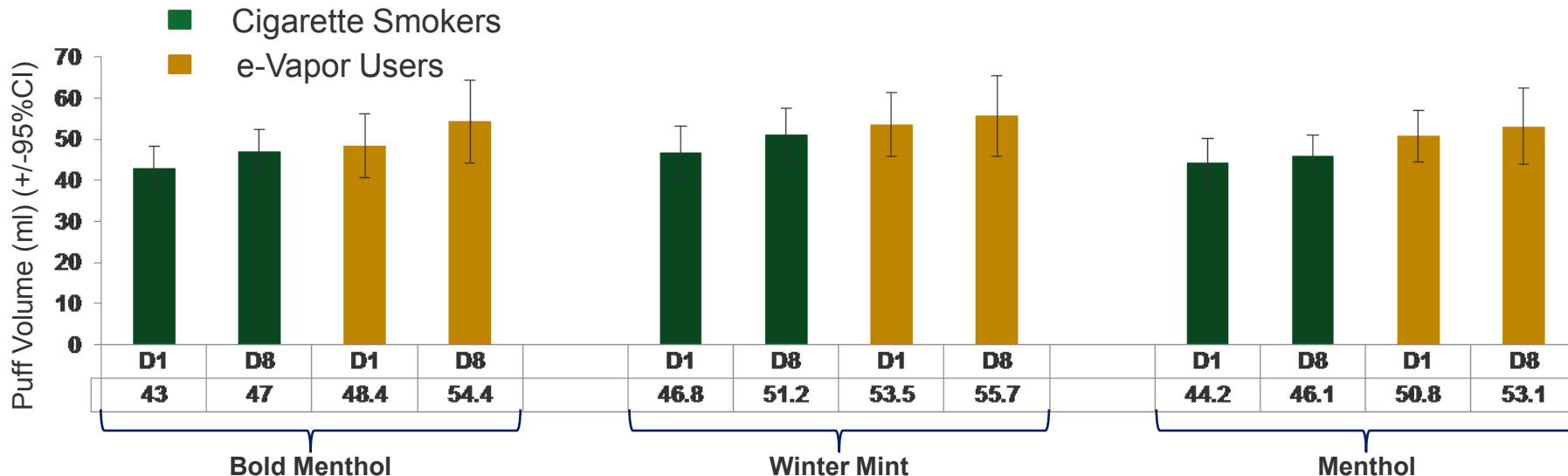
Effect	P value
Smokers vs. e-Vapor Users	0.8728
Day 1 vs. Day 8	0.0026
Smokers or e-Vapor Users vs. Products	0.5328

Group 2: Average Puff Duration



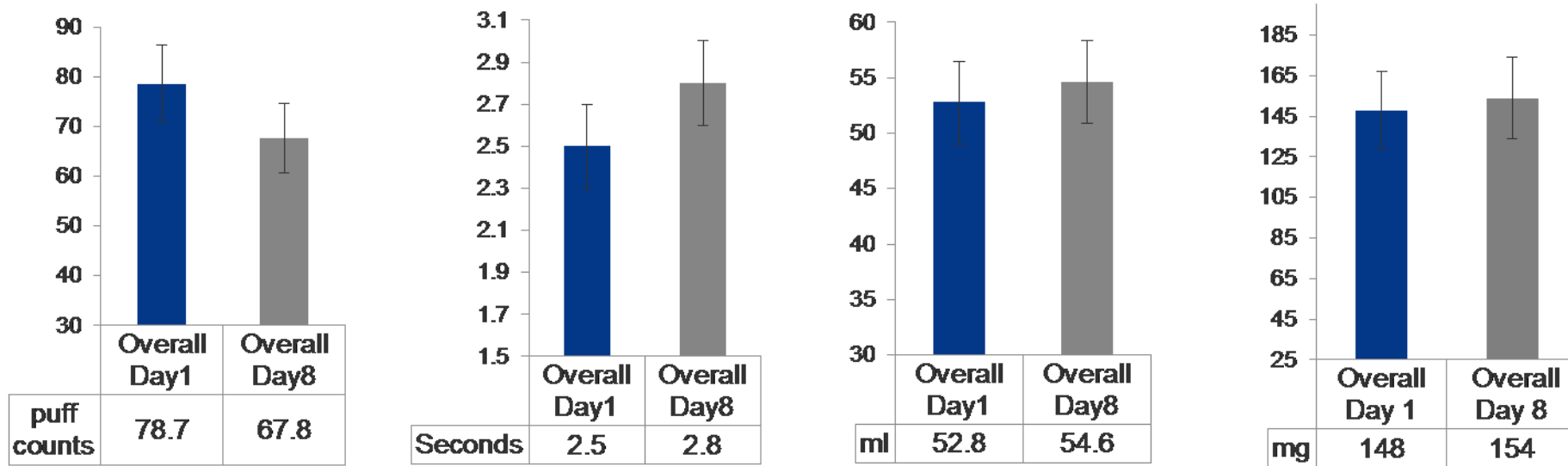
Effect	P value
Smokers vs. e-Vapor Users	0.0483
Day 1 vs. Day 8	<0.0001
Smokers or e-Vapor Users vs. Products	0.7198

Group 2: Average Puff Volume



Effect	P value
Smokers vs. e-Vapor Users	0.2608
Day 1 vs. Day 8	0.0006
Smokers or e-Vapor Users vs. Products	0.7323

Groups 1 and 2 Overall Average: Day 1 and Day 8



Although participants took fewer puffs on Day 8, they increased their puff duration and maintained the same level of e-Liquid use

Summary and Conclusions

- Within each Group, cigarette smokers used the different MarkTen® products similarly
- Within each Group, e-Vapor users used the different MarkTen® products similarly
- In general, e-Vapor users took longer puffs than cigarette smokers
- After 1 week acclimation to the products, both e-Vapor users and cigarette smokers took fewer puffs with longer duration while maintaining e-Liquid consumption





For copies of this presentation visit the Altria's Science Website at www.altria.com/alcs-science