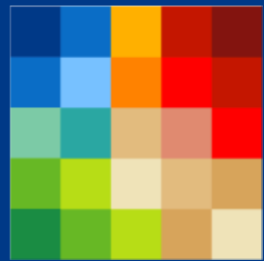


Cigarette Smoking Behavior among Adult Cigarette Smokers Using VERVE® Discs or Chews during 6-Weeks of At-Home Use

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Abstract

Background: FDA in its Draft Guidance for new tobacco product applications suggests that manufacturers include information regarding “...the frequency with which consumers use the product, and the trends by which consumers use the product over time” as well as “effects on... switching behavior...and dual use.” VERVE® Discs and Chews are oral tobacco-derived nicotine products that users chew and discard.

Method: To characterize VERVE® Discs or Chews use behavior and its influence on other tobacco use behavior, including switching and dual use, we conducted a 6-week, 2-phase, at-home use study in 517 adult cigarette smokers not planning to quit. Participants expressed interest in trying VERVE® products prior to enrollment in Phase 1 during which they tried two flavors (Blue Mint or Green Mint; 1 per day) of VERVE® Discs (n=256) or VERVE® Chews (n=261). During Phase 2, participants had open access to both flavors of either VERVE® Discs or Chews and chose the amount to take home and use over 6 weeks. Daily surveys captured number of cigarettes, number of Discs or Chews (by variety), and amount of other tobacco products (e.g. cigars, e-vapor, pipes etc.) used per day. An end-of-study survey captured current tobacco use status and quitting intentions.

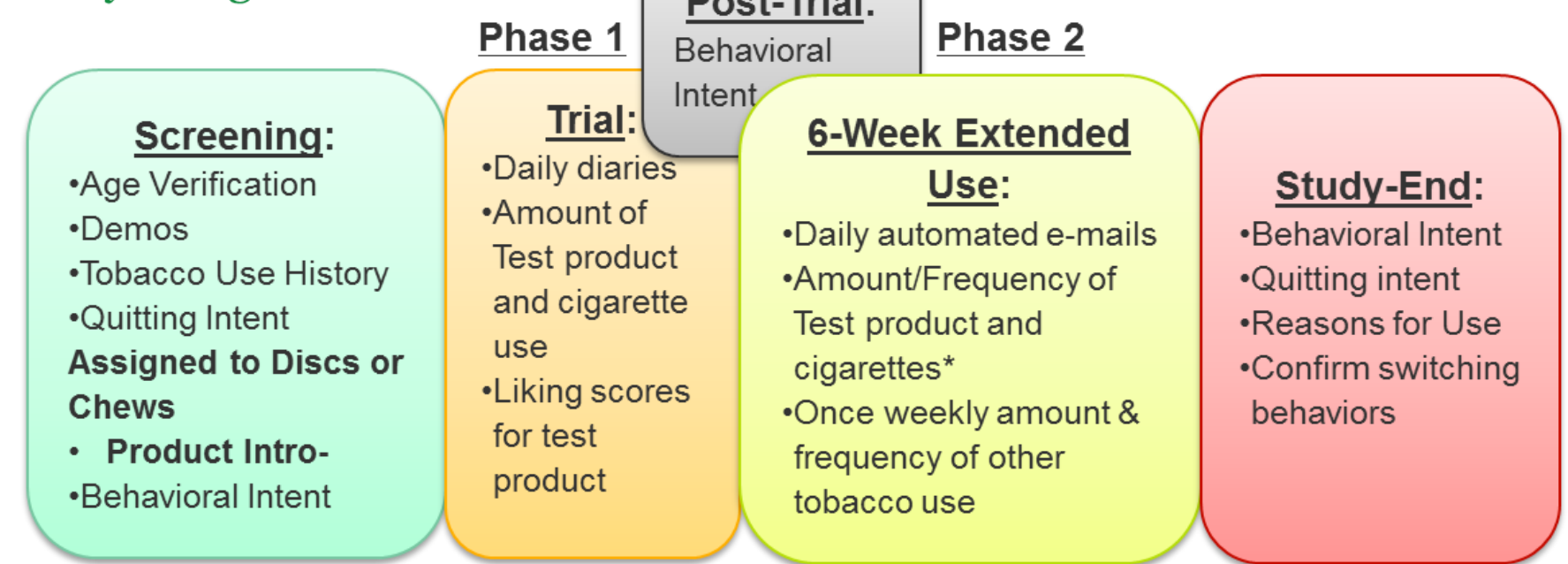
Results: By Week 6 of Phase 2, 23.2% of smokers switched to VERVE® (e.g. reported zero cigarettes), 59% reported a 20% or greater decrease from baseline in cigarettes smoked per day, 11.4% remained the same, and 6.4% increased smoking. Conclusion: A large portion of study participants dual used VERVE® with cigarettes; however, the majority either reduced smoking or switched completely after they started using VERVE® under these open access conditions. This is an interesting result given that participants had no intentions to quit smoking at screening. These results suggest that use of VERVE® can coincide with reductions in cigarette smoking, and possibly complete switching among adult cigarette smokers who express initial interest in trying and using the product.

Methods

Study Methods:

Participants were assigned to a single VERVE® form (Discs or Chews) at screening. Participants scored a three or higher on a 6-point “intention-to-try” scale for VERVE® Disc or Chew products prior to enrollment in Phase 1. During Phase 1, participants tried 2 branded flavor varieties (Green or Blue Mint; 1 per day) of their assigned form during a two-day trial. Participants returned for a post-trial visit. Only those who scored a three or higher on a 6-point “intention to use” scale continued to Phase 2. During Phase 2, participants had access to both flavor varieties of their assigned form and chose the amount and varieties to take home and use over 6 weeks. Daily surveys captured amount of cigarettes, number of VERVE® Disc or Chew pieces used, and other tobacco use.

Study Design and Measures



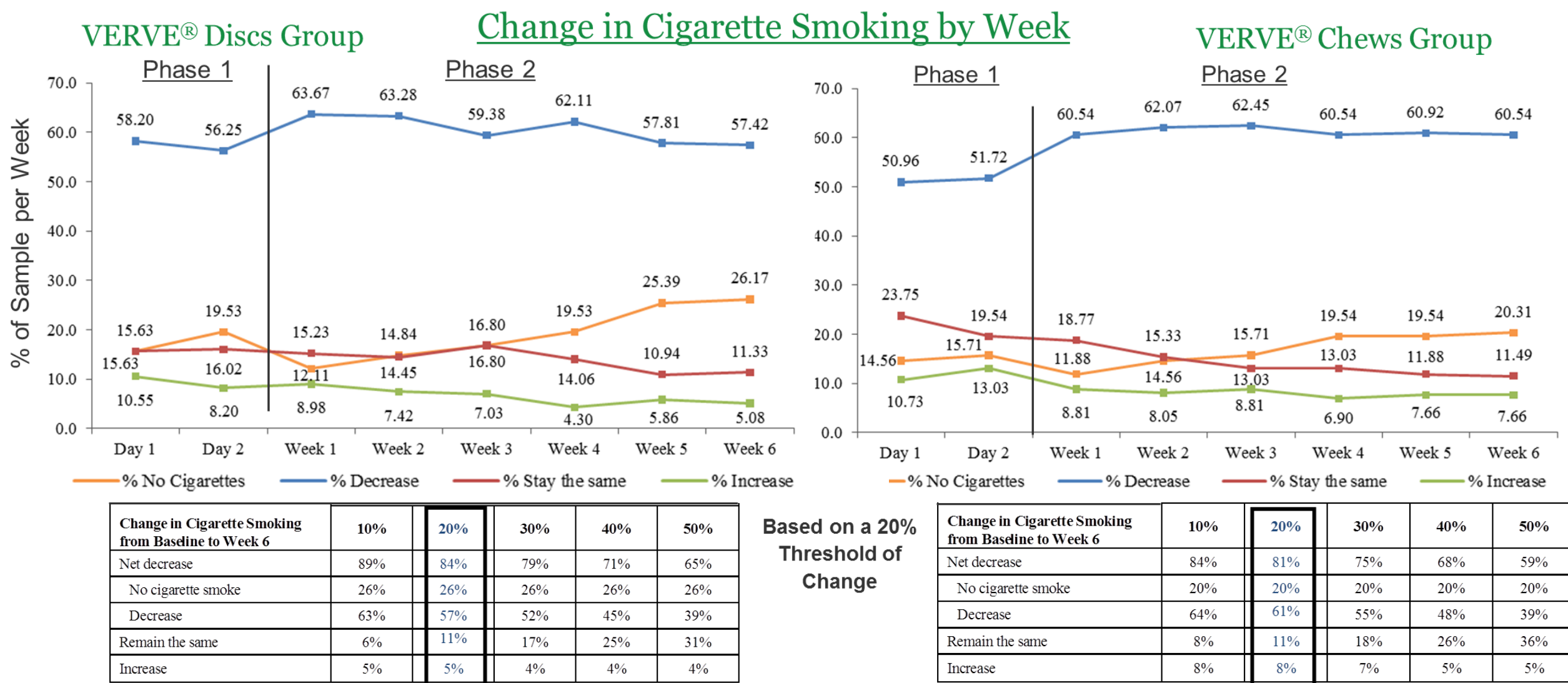
- ☐ Behavioral Intentions: Intention to try, use, dual use, switch to the test product
- ☐ Liking score: 7-point hedonic liking scale
- ☐ Amount: # of Verve® Discs/Chews per day; # of cigarettes per day; Frequency: # of days per week
- ☐ Quitting Intentions: Intentions to quit cigarettes/all tobacco in the next 3 months (screening) or 30 days (study-end)

Demographics and Tobacco Use

| DEMOGRAPHIC CHARACTERISTIC | VERVE® Discs Group | VERVE® Chews Group |
|-------------------------------------|--------------------------------------|------------------------------------|
| BASE (Total Sample Completed Study) | n = 256 | n = 261 |
| Gender | 51.6% Female | 50.2% Female |
| Age | | |
| 18-24 | 10.2% | 12.3% |
| 25-34 | 28.9% | 25.3% |
| 35-54 | 46.1% | 43.3% |
| 55-64 | 14.8% | 19.2% |
| Median Age | 38 years | 38 years |
| Race/Ethnicity | 68% White, 18% Black | 71% White, 20% Black |
| Education | 65.2% Some College+ | 64.4% Some College+ |
| Employment | 75% Employed | 72.8% Employed |
| Median Income (Range) | \$40-49K | \$40-49K |
| Geographic Region | 17.2% NE; 31.6% S; 28.5% MW; 22.7% W | 19.9% NE; 33% S; 24.5% MW; 22.6% W |

| Tobacco Use Behavior Reported at Screening | VERVE® Discs Group | VERVE® Chews Group |
|---|--------------------|--------------------|
| BASE (Total Sample Completed Study) | n = 256 | n = 261 |
| Smoking Frequency | 84% Daily | 76.6% Daily |
| # Days Smoked in Past 30 (mean ± S.D.) | 26.7 ± 6.5 | 26.3 ± 7.2 |
| # Cigs Smoked per Day Past 7 (mean ± S.D.) (Served as BASELINE smoking value) | 13.5 ± 11.8 | 12.7 ± 11.2 |
| Current Past 30-day Use of Other Tobacco (% of Sample) | | |
| E-Vapor | 32.8% | 31.8% |
| Cigars | 38.7% | 39.5% |
| Pipes (included water pipe) | 16.4% | 21.5% |
| Chewing Tobacco | 7.8% | 10% |
| Dip/Snuff | 10.9% | 8.8% |
| Snus pouches | 6.3% | 10% |

Results



Behavioral Outcomes of Dual Use, Smoking Reduction, and Switching – Study End

| Behavioral Outcome at Week 6 – Phase 2 (End of Study) | Total Sample n = 517 | VERVE® Discs Group n = 256 | VERVE® Chews Group n = 261 |
|---|----------------------|----------------------------|----------------------------|
| *Started using* ¹ VERVE® Discs or Chews | 100% | 100% | 100% |
| *Started using* ¹ VERVE® Discs or Chews AND still ² using cigarettes (Dual Use) | 74.8% | 71.5% | 78.2% |
| *Started using* ¹ VERVE® Discs or Chews AND reduced ³ cigarette smoking (Reduced) | 58.4% | 56.6% | 60.2% |
| *Started using* ¹ VERVE® Discs or Chews AND stopped smoking cigarettes AND still using VERVE® (Switched) | 23.2% | 25.8% | 20.7% |
| Other tobacco product use | N = 270 | N = 133 | N = 137 |
| Completely stopped using all “other” tobacco products ⁴ | 78.2% | 76.7% | 79.6% |

¹ Start Using defined as having used 20+ VERVE® Discs or Chews during Phase 2
² Still Using defined as using the product on any day in Week 6; Dual Use: Continued smoking cigarettes and still using VERVE® Discs or Chews at the end of phase 2
³ Reduced defined as 20% or greater reduction from number of cigarettes reported smoking in past 7 days at screening
⁴ Stopped using other tobacco products defined as no use (other than cigarettes and VERVE®) during Week 6

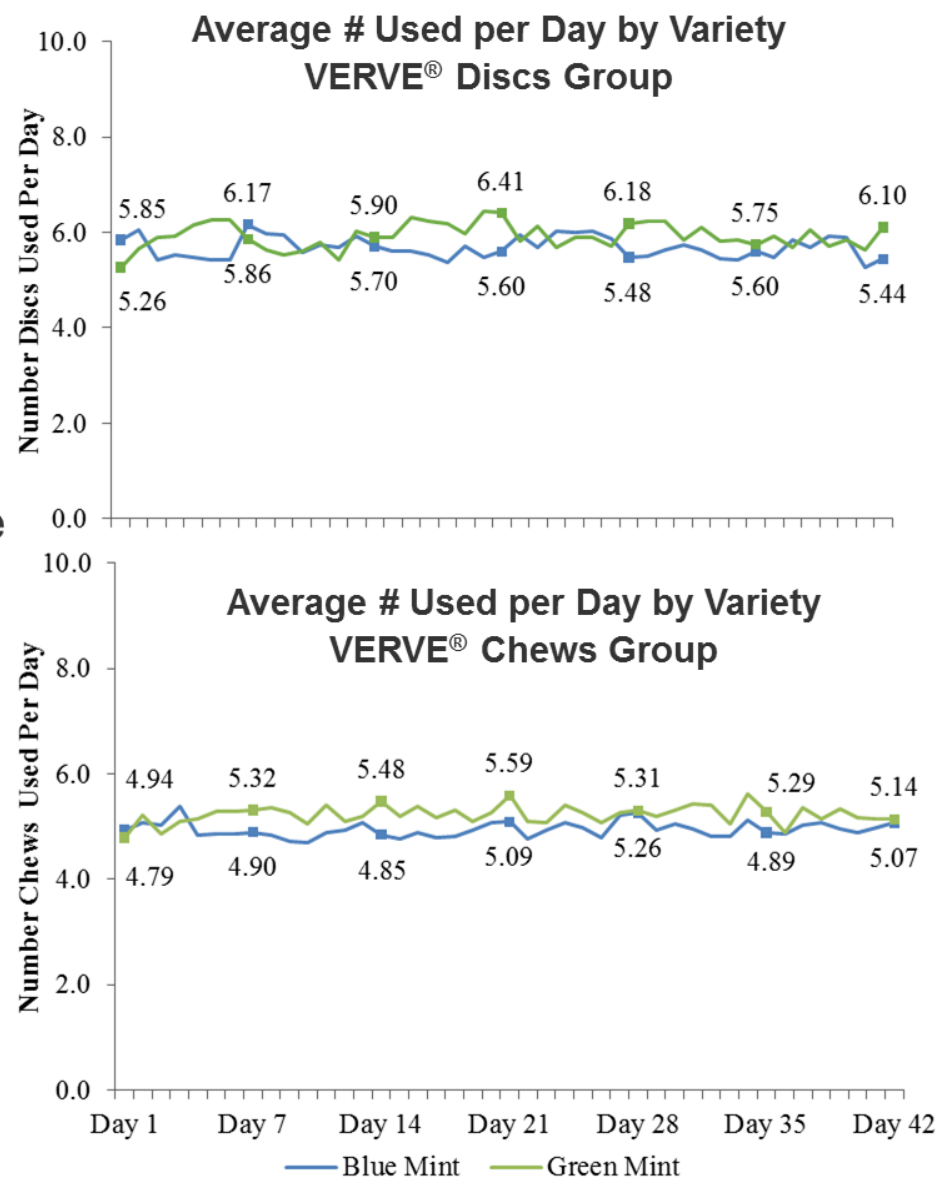
Conclusions

- A large portion of study participants dual used VERVE® with cigarettes; however, the majority either reduced smoking or switched completely after they started using VERVE® under these open-access conditions.
- This is an interesting result given that participants reported no intentions to quit smoking at screening.
- These results suggest that use of VERVE® can coincide with reductions in cigarette smoking, and possibly complete switching among adult cigarette smokers who express initial interest in trying and using the product.

% of Total Sample Reporting No, Single, or Multiple Tobacco Use by Week

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 |
|---|--------|--------|--------|--------|--------|--------|
| Base (Completed Phase 2) | n=517 | n=517 | n=517 | n=517 | n=517 | n=517 |
| Tobacco Use Behaviors | | | | | | |
| VERVE® Discs/Chews only | 7.35 | 10.64 | 11.80 | 14.70 | 16.44 | 17.41 |
| Cigarettes only | - | - | 0.19 | 0.39 | 0.39 | 1.35 |
| Other tobacco products only (excluding VERVE® Discs/Chews and cigarettes) | - | - | - | 0.19 | - | - |
| Cigarettes + other tobacco products only | - | 0.19 | 0.19 | - | - | - |
| VERVE® Discs/Chews + cigarettes | 67.89 | 69.05 | 68.86 | 66.54 | 65.57 | 64.41 |
| VERVE® Discs/Chews + other tobacco products | 5.03 | 4.64 | 5.03 | 5.03 | 6.19 | 5.80 |
| VERVE® Discs/Chews + cigarettes + other tobacco products | 19.73 | 15.47 | 13.93 | 12.96 | 11.03 | 10.44 |
| Did not use any tobacco products | - | - | - | 0.19 | 0.39 | 0.58 |

Amount of VERVE® Product Use



SUMMARY

- By Week 6 of Phase 2:
 - Over 20% of smokers had switched from cigarette smoking to VERVE® Disc or Chew use.
 - Over 55% of participants had reduced cigarette smoking by 20% or greater.
- VERVE® Disc or Chew use remained relatively stable across the 6-week usage period, with little variation between form or variety in amount of consumption.
- Similar reductions in cigarette and other tobacco product use occurred in the VERVE® Discs and Chews groups.
- Gradual declines in the percent of total sample engaged in cigarette smoking behavior and dual and poly tobacco use were observed during Phase 2.

Intentions to continue using VERVE® Discs or Chews – End of Study

94% of current VERVE® Disc/Chew users said they were somewhat, very, or extremely likely to use VERVE® Discs/Chews in the future

Over 40% of the total sample said they would definitely buy VERVE® Discs/Chews

Over 30% of the total sample said they would probably buy VERVE® Discs/Chews

Top Reasons for Continued Use of VERVE® Discs/Chews Smoking-Related Reasons:

- Cut back/quit smoking-58%
- Satisfy nicotine cravings-55%
- Less harmful to others-45%
- Use where I can't smoke-45%

General Reasons:

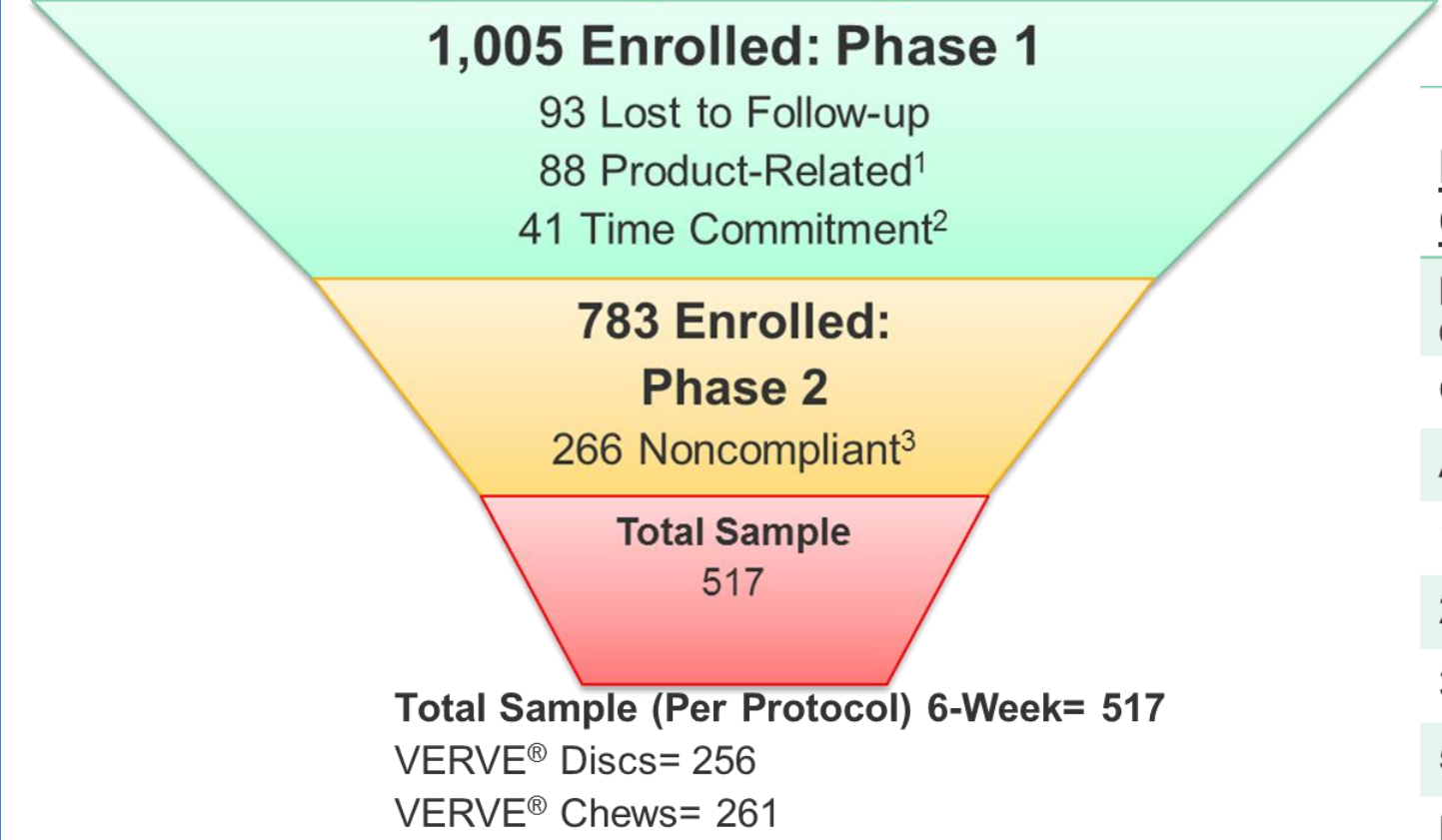
- Convenient/easy to use-55%
- Has a flavor I like-49%
- Enjoy the taste-44%

SUMMARY

Participants expressed continued interest in VERVE® Disc or Chew use at the end of the study, reasons for which included smoking reduction, nicotine satisfaction, and taste/flavor.

FINANCIAL DISCLOSURE: This study was funded by Altria Client Services LLC

Study Sample Disposition:



¹ Product-related reasons: Did not use test product during trial or not willing to use test product again
² Time commitment: Refused participation in Phase 2 due to time commitment
³ Noncompliant: Did not respond to 5 or more daily surveys in a row, or missed >2 day 7 surveys, despite reminders or did not complete at least 36 daily surveys.

Study Design:

We conducted a prospective, observational 6-week, 2-phase, at-home use study among 517 adult cigarette smokers not planning to quit.