

Bidi Vapor LLC
Bidi Vapor PMTA Scientific Study Summary¹
(Rev. August 2022)

I. Completed Research Included in September 2020 PMTA Submission

Cardno Electronic Nicotine Product Use Survey Results: Combined Consortium Findings (August 2020)

Study Design

Bidi Vapor LLC (“Bidi Vapor”) participated in a coalition with other U.S. electronic nicotine delivery system (ENDS) companies to gather ENDS-category specific information from a broad sample population of nearly 10,000 U.S. consumers. Survey questions were developed with the assistance of an independent, third-party laboratory (Cardno ChemRisk LLC) to ensure survey validity and accurate measurement.

Key Findings

The average BIDI® Stick user is a middle-aged adult.

- The mean age of all survey respondents was 45.

Most current ENDS users are former cigarette smokers.

- A majority of the respondents (71%) reported that they are current ENDS users and former cigarette smokers.

The majority of those who use ENDS have stopped or reduced smoking.

- A majority of the respondents (77%) who have smoked 100 or more combusted cigarettes in their lifetime confirmed that they stopped smoking.
- For dual users, 63% reported that they have not smoked a single cigarette in the past 30 days.

Flavors appeal to adult smokers more than tobacco or menthol.

- “Fruity” flavor was the number one flavor preference by approximately 50% of all respondents.
- Mint/menthol and tobacco were preferred by 33% and 28% of all respondents, respectively.
- Only about 3% of all respondents stated that they preferred no flavor, confirming that flavors appeal to adults and could serve an important role in transitioning current adult users away from more harmful combustible cigarettes.

¹ This Research Summary does not include Bidi Vapor’s other product-specific studies, including analytical studies, Harmful and Potentially Harmful Constituent (HPHC) assessments, toxicologic assessments, stability studies, etc. that are included in Bidi Vapor’s PMTA submissions.

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Bidi Vapor Electronic Nicotine Product Use Survey Results (August 2020)

Study Design

Bidi Vapor administered this survey to its consumer base to support its premarket tobacco product application (PMTA) submission. Survey questions were independently designed and analyzed by Cardno ChemRisk LLC. This survey tackles the electronic nicotine product usage and preferences of each BIDI® Stick user. 195 Bidi Vapor consumers were asked questions in an online survey around these topics:

- Tobacco product usage
- Electronic nicotine product usage

Key Findings

The average BIDI® Stick user is a middle-aged adult.

- The mean age of all survey respondents was 46.

More than half of BIDI®Stick users have stopped or reduced smoking.

- Over half of the respondents (53%) reported complete cessation of combustible cigarettes.

Over half of the respondents stated that they prefer ENDS over cigarettes due to flavors.

- About 59% of the respondents said the main reason they prefer ENDS over combustible cigarettes is due to flavor availability.

Flavors appeal to adult smokers more than tobacco or menthol.

- Approximately 84% of the respondents stated that they prefer fruity flavors compared to tobacco or menthol. This is compared to 49% who reported that they prefer mint/menthol, and only about 5% who reported that they prefer tobacco.

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Survey on BIDI[®] Stick Usage and Potential Impact (August 2020)

Study Design

Bidi Vapor administered another survey to its consumer base focusing on BIDI[®] Stick Usage. 205 respondents participated in the survey. This survey tackles the potential impact of the BIDI[®] Stick in the user's lifestyle and vaping habits. 211 respondents were asked questions in an online survey around these topics:

- Tobacco product usage
- BIDI[®] Stick usage

Key Findings

BIDI[®] Stick Users Are Generally Satisfied with the Product.

- All respondents (100%) reported being a current BIDI[®] Stick user.

More than half of BIDI[®] Stick users have stopped smoking.

- 53% of the respondents reported quitting smoking.
- 54% reported being “highly unlikely” to use cigarettes again after using the BIDI[®] Stick.

Technomic, Inc. Vape Consumer Insights Survey (September 2020)

Study Design

Bidi Vapor commissioned an online survey through Technomic, Inc., a third-party research organization. The Consumer Insight Survey is designed to assess, among other things, the impact of flavors, access, and nature of usage for ENDS. Survey questions were designed and analyzed by Technomic, Inc. Approximately 1,000 adult consumers (21+) participated in the survey.

Key Findings

A majority of ENDS users have stopped or reduced smoking.

- The majority (65%) of overall respondents reported that ENDS helped them quit or reduce their use of combustible cigarettes.
- 91% of converts report that electronic nicotine products helped them use fewer traditional cigarettes.
- Over half of dual users report using fewer cigarettes because of their use of electronic nicotine products.

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Technomic, Inc. Vape Consumer Insights Survey (September 2020) (Con't)

Key Findings (Con't)

Nicotine concentration plays a significant role in helping adult consumers transition away from combustible cigarettes.

- 79% of the respondents reported that the level of nicotine in ENDS played an important role in helping them quit or reduce combustible cigarette use.

Flavored products supported nearly half of adult consumers as they quit or reduce combustible cigarette use.

- About 47% reported that use of flavored ENDS helped them to quit or use fewer combustible cigarettes.

Most adult consumers perceive ENDS to be less harmful than combustible cigarettes, indicating that this could be a potential driving factor for switching.

- Most adult consumers (60%), particularly converts, believe that ENDS are less harmful than combustible cigarettes. However, about one-third of consumers (32%) perceive ENDS to be as harmful as combustible cigarettes, indicating that consumers are aware that use of BIDI[®] Stick is not without risk.

ENDS may help significant number of adult consumers who have found medically approved nicotine replacement therapies to be ineffective.

- Almost half of users (46%) who have tried medically approved nicotine replacement therapies found them ineffective
- About four in 10 users (39%) report that they miss the smoking sensation.
- These data points highlight the role that ENDS can play in helping those who have not had success with conventional nicotine replacement therapies or who miss the sensation imparted by use of combustible cigarettes.

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II. Post-PMTA Completed Studies (Data Submitted To FDA As PMTA Amendments)

Technomic, Inc. Disposable Vape Consumer Survey for Bidi Consumer Insights (December 2020)

Study Design

Bidi Vapor commissioned a second survey through Technomic, Inc., that incorporated measures specific to the following: Bidi Vapor LLC, BIDI® Stick, and disposables. Survey questions were designed and analyzed by Technomic, Inc. The survey was developed as a custom online structured survey administered to a sample of 1,000 consumers ages 21+ who use ENDS and an oversample of 500 users in Alabama, Georgia, and Tennessee. The research provides valuable consumer insights around disposable ENDS relative to other products, as well as user perspectives on the BIDI® Stick brand. The study incorporated recommendations from the FDA's draft TPPI guidance, including the inclusion of cognitive interview questions in the soft launch and development of measures to avoid bias. Specifically, the quantitative survey was designed to be objective in covering consumer perspectives on ENDS type selection decision drivers, including user knowledge of various product types and prioritized attributes; user demographic profiles by product type; awareness, perceptions and usage of BIDI® Stick relative to other disposable products; Bidi user demographics; and perspectives on underage use, counterfeit products, flavored product restrictions and other market dynamics.

Key Findings

Flavored ENDS or ENDS with a 6% nicotine level help consumers transition away from combusted cigarettes.

- Nearly a third (27%) of BIDI® Stick users report that flavored products are helping them to use combustible cigarettes less frequently.
- Nearly one-fourth (23%) of dual users reported that the 6% nicotine concentration is helping them to use fewer combustible cigarettes.

Bidi outperforms others for non-counterfeit authentication methods, adult-only positioning, customer service, and device recyclability.

- Compared to NJOY and Puff Bar, Bidi rated higher for these attributes.

Disposables are the least likely ENDS type to be used as a consumer's primary ENDS device

- Open system ENDS, in contrast, are the primary device type for almost half (47%) of consumers.

Bidi awareness and usage is the lowest among all brands listed

- Brand awareness was highest for JUUL, followed by Blue, Vuse, NJOY, Logic, Puff Bar, and finally BIDI® Stick, suggesting potentially low general awareness or popularity for the BIDI® Stick with youth also.

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Cerner Enviza BIDI® Stick Patterns of Use Study (December 2021)

Study Design

Bidi Vapor commissioned a Patterns of Use (“POU”) behavioral study on the BIDI® Stick through Kantar Health, LLC (now Cerner Enviza division of Cerner Corporation). Approximately 250 current adult (age 21+) BIDI® Stick users participated utilizing a retrospective, self-reported, cross-sectional design to measure recalled BIDI® Stick and Tobacco/Nicotine Product (TNP) usage and perceived TNP health risks among current users of BIDI® Stick. Data collection occurred between April and August 2021. Specifically, the study addressed usage habits, devices used, potential switching and absolute/relative health risks versus other tobacco/nicotine products.

Key Findings

Users of conventional tobacco products, such as combustible cigarette smokers, are willing to: (1) try and (2) continue use of the BIDI® Stick, specifically for substitution of other tobacco products.

- If BIDI® Stick were no longer available for purchase, over 10% of exclusive BIDI® Stick users reported that they would relapse to smoking combustible cigarettes.

Users of BIDI® Stick may be using the product in substitution for their other TNP such as combustible cigarettes.

- Over 60% of current BIDI® Stick users who reported prior combustible cigarette use had not smoked in the past 30 days.
- Among those respondents, 14.4% (n=33) reported no current use of any tobacco products, except for BIDI® Stick, and thus had completely substituted their use with BIDI® Stick.

Respondents view BIDI® Stick to have a lower health risk than combustible cigarettes, the same health risk as other ENDS, and a greater health risk than not using any TNP.

Current use of BIDI® Stick was driven largely by: (1) availability of flavors and (2) perceived to be less harmful to their health than combustible cigarettes.

- Among flavored BIDI® Stick products most often used, nearly 80% of current BIDI® Stick users reported using predominantly non-tobacco and non-menthol flavors.
- Only 1.6% of current BIDI® Stick users reported using the tobacco-flavored Classic BIDI® Stick most often.
- Most respondents (62%) reported that the availability of flavored BIDI® Stick products was a “Very important” or “Extremely important” factor in their decision to start using the BIDI® Stick.

Flavors play an important role for adults looking to quit smoking.

- Among respondents who expressed an intention to completely replace cigarette smoking, 64.0% reported that impact of BIDI® Stick flavor was “Extremely helpful” and 28.0% reported it as a “Very helpful” factor.

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Cerner Enviza BIDI[®] Stick Likelihood of Use Study (December 2021) – Submitted for Publication in *Harm Reduction Journal* in August 2022; Research Square preprint: <https://www.researchsquare.com/article/rs-1962398/v1>.

Study Design

Bidi Vapor also commissioned a Likelihood of Use (“LOU”) tobacco product perception and intention (TPPI) study on the BIDI[®] Stick through Kantar Health/Cerner Enviza. The BIDI[®] Stick LOU study was administered to a broader sample (N=2,820 respondents) of adult participants (age 21+) using a web-based, quantitative survey to assess tobacco use behavior, perceptions, and intentions. The LOU study characterized consumer perceptions of BIDI[®] Sticks and assessed the likelihood of increased or decreased use of tobacco/nicotine products after becoming aware of BIDI[®] Sticks among nonusers and users groups, separated by age groups and their usage history of tobacco/nicotine products (TNP). Study cohorts included never TNP users, former TNP users, current cigarette smokers with intention to quit, current cigarette smokers without intention to quit, and current ENDS users. Young adults (ages 21-24 years) group served as proxy for youth (< 21 years) consistent with FDA’s PMTA Final Rule. The survey was fielded between May and August 2021.

Key Findings

Study findings suggest low appeal of the BIDI[®] Stick to all cohorts, including non-users, former users, and youth, across all flavors (flavored, tobacco flavored, and menthol flavored products), supporting that the continued marketing of the BIDI[®] Stick would be appropriate for the protection of the public health

TNP non-users, both former and never users, reported *no interest* in using BIDI[®] Stick based on average Juster scale ratings below 1.0 on the 11-point scale, representing “no chance” of using the product. This finding was consistent for all BIDI[®] Stick flavors being assessed.

Young adult TNP non-users’ intentions to use BIDI[®] Stick were not significantly different than that of adult TNP non-users.

○ Young adult TNP non-users reported no interest in using BIDI[®] Stick as based on average Juster scale ratings below 1.0 on the 11-point Juster scale, representing “no chance” of using the product. ***This finding was the same regardless of the BIDI[®] Stick flavor being assessed.*** FDA has stated that young adults’ behavior may serve as a surrogate for youth behavior.

More than half of all current cigarette smokers reported that they would have an interest in trying the BIDI Stick to move away from combustible cigarettes.

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Clinical Pharmacokinetics/Abuse Liability Study (December 2021) - Published

Study to assess BIDI[®] Stick pharmacokinetics and subjective effects in adult smokers. The BIDI[®] Stick is a disposable ENDS product which contains 6% nicotine benzoate salt and is marketed in 11 flavors (a tobacco flavor, menthol flavor, and 9 other flavors).

Primary Objectives

- To determine kinetics of nicotine absorption into the blood of subjects when they smoke a combustible cigarette, use the BIDI[®] Stick ENDS with varying flavors, or use JUUL ENDS.
- To characterize subjective effects after use of the BIDI[®] Stick ENDS, JUUL ENDS, and a combustible cigarette.

Key Findings

- BIDI[®] Stick delivered nicotine similarly to a cigarette (90-100%).
- ENDS products and a Heat-not Burn product delivered less nicotine than a cigarette (50-70% respectively).
- BIDI[®] Stick is as satisfying as a cigarette.
- BIDI[®] Stick relieves cravings for nicotine like a cigarette.
- Participants liked BIDI[®] Stick as much as their cigarettes.
- Data suggest that abuse liability of BIDI[®] Stick is lower than combustible cigarettes.

BIDI[®] Stick offers a far more effective and satisfying nicotine delivery alternative to combustible cigarettes for adult smokers compared to JUUL. For adult tobacco users and smokers, BIDI[®] Stick delivers nicotine more effectively than Vype ePen3, Vuse Solo, myblu, and tobacco heating products including FDA-authorized IQOS. No serious adverse events occurred during the study.

BIDI[®] Stick ENDS may be a satisfying alternative to cigarettes among current adult smokers, including those who find it difficult to quit or who are not interested in quitting smoking. Results of a recently published randomized placebo-controlled trial (“RCT”) concluded that “ENDS with

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Clinical Pharmacokinetics/Abuse Liability Study (December 2021) – Published (Con't)

nicotine delivery approaching that of a cigarette are more effective in enabling ambivalent cigarette smokers to quit smoking.”²

A comprehensive range of flavored BIDI[®] Stick ENDS do not differentially impact nicotine pharmacokinetics or abuse liability/dependence measures when compared to tobacco flavored BIDI[®] Stick ENDS.

- Bidi Vapor’s analyses of pharmacokinetic data found no difference in nicotine pharmacokinetics between BIDI[®] Stick ENDS containing different flavors. This is significant because it appears that only a small number of studies have assessed the impact of ENDS flavors on nicotine pharmacokinetics.

ClinicalTrials.gov identifier: <https://clinicaltrials.gov/ct2/show/NCT05072925>

Study Publication: Fearon, I.M. et al. A Randomised, Crossover, Clinical Study to Assess Nicotine Pharmacokinetics and Subjective Effects of the BIDI Stick ENDS Compared with Combustible Cigarettes and a Comparator ENDS in Adult Smokers; November 24, 2021 (DOI: <https://doi.org/10.21203/rs.3.rs-1106788/v1>) (available at <https://assets.researchsquare.com/files/rs-1106788/v1/1c4725d1-7a50-4790-aa9c-e3b1492f9ac1.pdf?c=1637787276>).

² Foulds J, Cobb CO, Yen MS, Veldheer S, Brosnan P, Yingst J, Hrabovsky S, Lopez AA, Allen SI, Bullen C, Wang X, Sciamanna C, Hammett E, Hummer BL, Lester C, Richie JP, Chowdhury N, Graham JT, Kang L, Sun S, Eissenberg T. Effect of Electronic Nicotine Delivery Systems on Cigarette Abstinence in Smokers with no Plans to Quit: Exploratory Analysis of a Randomized Placebo-Controlled Trial. *Nicotine Tob Res.* 2021 Nov 26:ntab247. doi: 10.1093/ntr/ntab247. Epub ahead of print. PMID: 34850164.

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Nationally Representative Bidi Vapor Perceptions and Behavioral Intentions Study of the BIDI® Stick E-Cigarette (May 2022) – [Planned for Publication]

Study Design

Bidi Vapor worked with Dr. Christopher Russell of Russell Burnett Research and Consultancy Ltd and McKinney Regulatory Science Advisors, LLC to conduct a Perceptions and Behavioral Intentions Study (“PBI”) Study, a cross-sectional, internet- based, product-specific survey study of risk perceptions and behavioral intentions in relation to the BIDI® Stick ENDS in 11 flavor profiles among a broad (~7,000), U.S. nationally representative samples of adult current combusted cigarette smokers, former smokers, and non-smokers. Subjects were recruited from Ipsos-Insight, LLC’s Knowledge Panel®, the largest probability-based online research panel in the United States.

This study provides estimates of the probabilities that legal age adults will trial the BIDI® Stick ENDS in each flavor option if marketed in the United States. Specifically, survey questions addressed: intentions to trial and regularly use BIDI® Stick 11 flavor profiles; perceptions of the health and addiction risks of using BIDI® Stick 11 flavor profiles; and comprehension of information presented in the label of 11 BIDI® Stick flavor profiles. The study includes a direct comparison measure assessing the BIDI® Stick flavors that are most likely to be used by Current Smokers as a partial or complete replacement for cigarettes, providing a comparison between the benefit of flavored versus tobacco-flavored ENDS to adult smokers in transitioning away from cigarettes. ***Results of the PBI study are expected to be submitted for publication Q4 2022.***

Key Findings

Non-smokers, including young adults serving as a proxy for youth, generally showed low intention to try the BIDI® Stick across all flavors.

- Exposure to the BIDI® Stick ENDS generated high levels of positive intention to trial a BIDI® Stick ENDS among legal age adults who are Current Smokers and/or Current Users of e-cigarettes – *i.e.*, the intended users of the BIDI® Stick ENDS.
- Exposure to the BIDI® Stick ENDS simultaneously generated low levels of positive intention to trial the BIDI® Stick ENDS among legal age adults who have never smoked, have never regularly smoked, or do not currently smoke conventional cigarettes and/or use e-cigarettes.
- Current Smokers perceived a switch from smoking cigarettes to using a BIDI® Stick ENDS as the third-best option available to them behind a switch to nicotine replacement therapy (NRT) products (second-best option) and cessation of all tobacco and nicotine product use (best option).

Significantly, these study results were largely consistent across all 11 flavor profiles.

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III. Current Research

CSUR ENDS Population Prevalence Study (Start Date May/June 2022; Final Report Expected August 2022) [Planned for Publication]

Study Design

As a result of FDA specifically recommending obtaining behavioral and actual use data on minors (18-20-year-olds), Bidi Vapor agreed to participate in the Centre for Substance Use Research (CSUR)'s independently funded cross-sectional, probability-based, whole-of-population online study called, "Prevalence of Use of 20 Electronic Nicotine Delivery System (ENDS) Brands Among Youth, Young Adults and Older Adults in the United States." Bidi Vapor participated in the second wave of the study (May/June 2022). Because it specifically includes youth (13-17 years old) and young adult (18-24 years old) cigarette and e-cigarette user groups, the study provides valuable actual use, over-time, comparative (*i.e.*, across the various BIDI[®] Stick flavors) data to support Bidi Vapor's PMTA and proposed post-market surveillance plans. The older adult sample will be drawn from Ipsos-Insights LLC's proprietary KnowledgePanel[®], the largest probability-based internet research panel in the United States that is designed to be representative of the non-institutionalized population aged 18 years and older. Bidi Vapor will not be provided with direct access to any data on youth. **Results of the Population Prevalence study are expected to be submitted for publication Q4 2022.**

Key Measures

The study's objective is to describe and characterize the prevalence and patterns of use of three tobacco product categories/devices among nationally representative samples of youth, young adults, and older adults within the United States. Specifically, the study will assess the prevalence of specific brand e-cigarettes and specific device usage, the prevalence of any e-cigarettes (all brands), and the prevalence of combustible cigarette use.

Preliminary Findings* (**Subject to Amendment Pending Completion of Final Data Analysis and Reporting*)

- 0% of 13- to 17-year-old individuals have used BIDI[®] Stick in the past 30 days.
- A small percentage (0.0 to 0.3%) of 18- to 20-year-olds use BIDI[®] Stick every day or some days.

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Bidi Vapor Real-World Data Project (Project Initiation Expected Q4 2022; Final Report Expected Q1 2023)

Study Design

Bidi Vapor is in discussions with Professional Datasolutions, Inc. (“PDI”) (which has now acquired Koupon Media) on collection of real-world data. Findings are expected to take into consideration conversion rates, flavor preferences, and other core, BIDI[®] Stick product-specific, real-world data intended to can address APPH factors. Research would be directed to the Koupon platform, which houses transactional data on BIDI[®] Sticks.

Key Measures

TBD

Preliminary Findings* (**Subject to Amendment Pending Completion of Final Data Analysis and Reporting*)

- PDI's initial assessment of the spending of adult smokers who also vaped showed a significant return to combustible cigarettes after the initial MDO-related ENDS flavor bans in 2020.