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## ***A Randomized, Controlled Study to Assess Biomarkers of Exposure in Adult Smokers Switching to Oral Nicotine Products***

November 2022 – *The Journal of Clinical Pharmacology* (JCP)

### ***Why is this article important to you?***

This open-label, randomized, controlled, in-clinic, six-parallel-group study evaluated changes in biomarkers of exposure (BoEs) to select harmful and potentially harmful constituents in adult smokers (n = 213) not planning to quit smoking. Adult smokers were randomized to continue smoking (CS), reduce smoking by 50% and dual use oral tobacco-derived nicotine products (VERVE chews/discs), stop smoking and exclusively use discs or chews or stop using all tobacco products (NT). The primary objective compared 24 hr urinary total 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL; a biomarker for the carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) in dual and exclusive use of discs and chews to CS and NT on Day 7. NNAL levels on Day 7 were significantly lower ( $p < .05$ ) among dual and exclusive users of discs/chews compared to CS; median percent reductions were  $\approx 30\%$  and  $\approx 73\%$ , respectively. NNAL levels were not significantly different between those who used discs/chews and the NT group. Many of the additional secondary BoEs were significantly lower in dual users (10/19) and exclusive users of discs/chews (17/19) compared to the CS group. Overall, reductions in secondary BoEs were greater in exclusive users than dual users. The 24hr urinary nicotine equivalents were significantly lower ( $p < .05$ ) among exclusive users of discs/chews compared to CS. Learners who complete this activity will be able to explain the relevance of biomarkers as important components of outcome assessment and articulate the scientific methods involved in the process of establishment of biomarkers.

### **ACPE Accreditation Statement**

The American College of Clinical Pharmacology® is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

**UAN:** 0665-0000-22-038-H01-P– ACPE 1 Contact Hours

**Activity Type:** Knowledge-based **Format:** Home-study **Target Audience:** 'P'



### **ACCME Accreditation Statement**

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### **ACCME Designation Statement**

The Accreditation Council for Continuing Medical Education designates this journal CE activity for 1 *AMA PRA Category 1™* credit. Physicians should only claim credit commensurate with the extent of their participation in the activity.

### **Target Audience**

Interprofessional team of Physicians, Pharmacists and PhDs.

### **Learning Objectives**

After completing this activity, the learner will be able to:

1. Explain the methods involved in conducting a randomized study;
2. Critically evaluate the results of such a study;
3. Explain the concept of internal and external validity.

### **Requirements to Receive Credit**

To receive continuing education credit, the learner must register for the educational activity, study the provided journal article and complete the online learning Post-event Self-assessment, as well as the online course Evaluation and CME/CPE Certificate. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the article, Post-event Self-Assessment and Evaluation. Contact [CE@ACCP1.org](mailto:CE@ACCP1.org) with any questions.

### **Disclosures:**

Article Selection: Joseph S. Bertino Jr, PharmD, planner for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

Planners: Nusrat Shafiq, MD, planner for this educational activity, has no relevant relationships with ineligible companies.

CE Reviewer: Jomy George, PharmD, reviewer for this educational activity, has no relevant relationship(s) with ineligible companies to disclose.

### **Schedule & Fees**

JCP monthly Journal CE articles are generally released on the 1<sup>st</sup> or 2<sup>nd</sup> Tuesday of each month. They are priced in packages of January to December for each year. Packages are available at no cost to ACCP Members and \$75/calendar year to Non-members. Once you register, you have access to all of the Journal CE articles for the calendar year.

### **Acknowledgement of Financial Support**

No financial support was received for this educational activity.

### **Home Study Initial Release and Expiration Dates**

**Date of Issuance:** 11/01/2022

**Expiration Date:** 11/01/2025

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### **Helpful Tips**

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