



Product Use Behaviour Sub-Group (PUB)

2022 Annual report

Coordinator: Dr Krishna Prasad (BAT)

Secretary/ SC Liaison: Dr Xavier Cahours (IMB)

2022 CORESTA CONGRESS ONLINE

10 – 28 October 2022



CORESTA PUB Sub-Group: Objectives

1. Critique and review published papers on all aspects of tobacco and related products' use behaviour, and publish in peer-reviewed journals.
2. Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.
3. Identify gaps in total knowledge and suggest suitable work to provide the necessary information.



PUB Sub-Group Meetings 2022

No	Date	Meeting	Time (UK)	Chair
1	25 May 2022	PUB SG 2022 spring virtual meeting	15:00 – 17:00	Dr. K Prasad & Dr. X Cahours
2	11 Sep 2022	PUB SG 2022 fall hybrid meeting US	08:00 – 11:30	Dr. K Prasad & Dr. X Cahours

The details of the topics discussed, timelines and plan of action are documented in the meeting minutes prepared by Xavier Cahours available on the CORESTA website.

Several other virtual meetings were held by the respective NWIP leaders to progress the projects in addition to CROM Task Force meetings & workshops were lead by Christelle Chrea.



Outline: 2022 Activities

1. PUB-156-NWIP: Abuse liability assessment review update - Complete
2. PUB-169-NWIP: VLNC review update – Complete
3. PUB-190-NWIP: Formation of CROM Task Force - Complete
4. PUB-273-NWIP: Definition of use behaviour and exposure terminology - Active
5. PUB-278-NWIP: Managing Data Generated by Connected Devices – Restarted
6. Next steps
7. New projects



1.0 PUB-156-NWIP



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-170306

To be completed by the Proposer

Proposal date (all dates in YYMMDD format): 170721
Proposer (Individual or Working Group) Krishna Prasad (PUB)
Submitted by: (Name, Organization): Michael Kong, Altasciences Clinical Research
On behalf of (Organization, if different from above): CORESTA

To be completed by the CORESTA Secretariat

Date Received by Secretariat: 170721
Reference number: 156
Date forwarded to the Scientific Commission 170724
Deadline for answer by Scientific Commission 170804

Prepare a position paper that summarizes current human abuse liability research as they relate to the development of tobacco products.

- applicability of abuse liability assessment methods used
- regulatory requirements and challenges
- novel tobacco-specific models or avenues of research needing attention.



Update – Project Completed

- ❖ Content of the review presented at TSRC

NWIP 268


- ❖ Manuscript reviewed by Nicotine and Tobacco Research

Major revisions requested

Revised manuscript submitted June 2021

- ❖ Manuscript accepted for publication by Nicotine and Tobacco Research

Online publication Sept 2021



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-191126

To be completed by the Proposer	To be completed by the CORESTA Secretariat
Proposal date (all dates in YYYYMMDD format): 200507	Date Received by Secretariat: 200507
Proposer (Individual or Working Group) Krishna Prasad, PUB Sub-Group	Reference number: #268
Submitted by: (Name, Organization): Sarah Baxter-Wright	Date forwarded to the Scientific Commission 200511
On behalf of (Organization, if different from above):	Deadline for answer by Scientific Commission 200515 OK 200518

74th Tobacco Science Research Conference



August 29-31, 2021
Boston, Massachusetts USA

2:20 PM

69. HUMAN ABUSE LIABILITY ASSESSMENT OF TOBACCO AND NICOTINE PRODUCTS: CONSIDERATIONS TO MEET CURRENT REGULATORY RECOMMENDATIONS. [Andrea VANSICKEL](#)¹, Sarah Baxter-Wright², Leanne Campbell², Neil Sherwood³ and Michael C. Kong⁴; ¹Altria Client Services, Richmond, VA USA, ²RAI Services Company, Winston-Salem, NC USA, ³Neil Sherwood Consulting, Nyon, Vaud Switzerland and ⁴Altasciences, Overland Park, KS USA



HAL Review Published

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Article Contents

Abstract

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ACCEPTED MANUSCRIPT

Human Abuse and Assessment of Tobacco and Nicotine Products: Approaches for Current Regulatory Recommendations

Andrea Vansickel, Ph.D , Sarah Baxter, Neil Sherwood, Michael Kong, Leanne Campbell

Nicotine & Tobacco Research, ntab183, <https://doi.org/10.1093/ntr/ntab183>

Published: 09 September 2021 **Article history** ▾

selected as the Editor's Choice paper for Nicotine and Tobacco Research



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2.0 PUB-169-NWIP



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-170306

To be completed by the Proposer

Proposal date (all dates in YYMMDD format):

170922

Proposer (Individual or Working Group)

Product Use Behaviour Subgroup

Submitted by: (Name, Organization):

Mohamadi Sarkar, ALCS

On behalf of (Organization, if different from above):

Product Use Behaviour Subgroup

To be completed by the CORESTA Secretariat

Date Received by Secretariat:

171023

Reference number:

169

Date forwarded to the Scientific Commission

171117

Deadline for answer by Scientific Commission

171127

Summarizes current knowledge on the potential impact of VLNC

To demonstrate:

A) estimated daily exposure level is at or below the actual human nicotine addiction threshold

B) critical number of current cigarette smokers who switch to use only VLNC products will quit

C) sufficient reduction in the number of non-smokers (especially youth) who initiate smoking VLNC



NWIP Closing Steps

- ❖ In line with CORESTA Board guidance the VLNC NWIP 169 closing report was compiled by Neil Sherwood July 2022
- ❖ The NWIP closing report has been forwarded by XC & KP with a recommendation to close the project to SC for review and approval Oct 2022.
- ❖ Neil has been charged with having a watching brief on the developments in this area and update the Sub-Group at regular intervals.

- ❖ The FDA Unified Spring 2022 Agenda includes a plan for proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and other combusted tobacco products. The timing of the associated rule remains uncertain: <https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco>
- ❖ The New Zealand Smokefree Aotearoa 2025 Action Plan aims to reduce smoking prevalence to less than 5% and proposes a mandated nicotine product standard. A Technical Expert Advisory Group is to report to the NZ Government by the end of 2023: <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-aotearoa-2025-action-plan>
- ❖ White CM, Tessier KM, Koopmeiners JS, et al., Preventive Medicine 2022. "...the extent to which cigarette nicotine reduction decreases smoking may depend on the reinforcing characteristics of alternative products, including the available nicotine contents and flavors of e-cigarettes."
<https://www.sciencedirect.com/science/article/abs/pii/S0091743522002626>



3.0 PUB-190-NWIP



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-170306

To be completed by the Proposer

Proposal date (all dates in YYYYMMDD format):
180503

Proposer (Individual or Working Group)
Krishna Prasad, PUB Coordinator

Submitted by: (Name, Organization):
Krishna Prasad, BAT

On behalf of (Organization, if different from above):

To be completed by the CORESTA Secretariat

Date Received by Secretariat:
180529

Reference number:
190

Date forwarded to the Scientific Commission
180530

Deadline for answer by Scientific Commission
180607 (SC meeting)

- Development and validation of Consumer Reported Outcome Measures (CROM) for the Global Tobacco Industry using a Consortium approach
- NWIP culminated in the formation of CROM Task Force approved by the Board
- Going forward the TF activities will be covered separately
- Project Completed



4.0 PUB-273-NWIP



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-191126

To be completed by the Proposer

Proposal date (all dates in YYMMDD format): 200728
Proposer (Individual or Working Group) Krishna Prasad PUB (Product Use Behaviour) Sub-Group
Submitted by: (Name, Organization): Lesley Giles, JT International SA
On behalf of (Organization, if different from above):

To be completed by the CORESTA Secretariat

Date Received by Secretariat: 200728
Reference number: #273
Date forwarded to the Scientific Commission 200729
Deadline for answer by Scientific Commission 200810 Approved 200819

1. To define the terms and methods used for assessing product use behaviour and tobacco exposure, with the objective of generating a uniform application of the terms used by scientists working in this field of research.
2. Update previously published (2013) 'Assessing Smoking Behaviour and Tobacco Smoke Exposure: Definitions and Methods' expanded to include use behaviour of products such as e-cigarettes, HTP and oral nicotine products.

- ❖ Approved by CORESTA Scientific Committee on August 2020
- ❖ The full program developed over a 1.5-year period.



- Set up a writing and review team for the project from PUB and BMK members.
- Identify and create a list of new vocabulary terms
- Prepare draft list of standard vocabulary, distribute for review
- Collect comments on list from review team
- Prepare draft paper based on the agreed standard vocabulary list, distribute for review
- Collect comments - review team & SG members **DONE**

Prepare final draft of paper (2022 Q2) **DONE**

- Distribute for review to the scientific commission (2022 Q3) **DONE Aug 22nd 2022**
- Collect comments from the scientific commission on final draft
- Revise final draft with SC comments & publish on CORESTA website
- Prepare draft for publication scientific journal. Candidate journal: Contributions to Tobacco & Nicotine Research (Formerly: Beiträge zur Tabakforschung International)



5.0 PUB-278-NWIP



New Work Item Proposal

STDS-002-CCA-C2_New Work Item Proposal-191126

To be completed by the Proposer

Proposal date (all dates in YYYYMMDD format):

Drafted 201504. Updated 201027

Proposer (Individual or Working Group)

Krishna Prasad – PUB Sub-Group

Submitted by: (Name, Organization):

Michael Capone, HAUNI

On behalf of (Organization, if different from above):

To be completed by the CORESTA Secretariat

Date Received by Secretariat:

201119

Reference number:

278

Date forwarded to the Scientific Commission

201123

Deadline for answer by Scientific Commission

201201 **Approved 201201**

1. Data. The data generated by connectable devices should provide manufacturers and/or its explicitly authorized partners the ability to monitor device performance and manage compliance.

2. Structure. The data should be formatted to allow processing by explicitly authorized partners for the purposes of conducting scientific investigations and performing benchmarking.

3. Communication. The data should be transmitted from the device to a companion mobile application or cloud platform using a common and secure protocol.

SME identified project re-started

❖ **Robert Underly (RAIS) identified to lead this project, he has reviewed the white paper and proposed some changes for a NWIP.**

The scope and purpose have been changed to encompass “all inhalable products” as opposed to just ENDS.

The scope has also been shifted away from devices after point of sale to connected devices for research purposes with a focus on why the data would provide value to consumer, regulatory bodies and the tobacco industry.

The data standards, security structures, and data privacy standards are to be written as “minimum requirements” to avoid limiting data collection for future devices.

❖ **Revised NWIP will be re-submitted for SC approval early 2023**

- ❖ Review WHO Study Group Report 1029 and consider the implications on PUB Sub-Group activities
- ❖ Align PUB Sub-Group long term plans to align with CORESTA strategy
 - 2 year plan
 - Define the terms and methods used for assessing smoking behaviour, exposure and abuse liability across product categories
 - Build comprehensive knowledgebase of all relevant work in the field of use behaviour for ENDS, HTPs and Oral Nicotine Products
 - 5 year plan
 - Investigate product use behaviour under "real" conditions for ENDS, HTPs and ONDs using connected device
 - Including recommended methods for managing data generated by connected devices



New Projects

1.0 Actual Use Study Design Review

❖ Background

- Tobacco regulators such as the US FDA require information to estimate the impact of a new product on public health prior to market authorization. Such information includes use behaviors and the likelihood that the new product displace use of other, higher risk, combustible products, after product introduction. There are challenges in obtaining this type of information for new products that are not yet authorized for sale (investigational tobacco products).

❖ Purpose

- No guidance on the design or conduct of studies has been shared via the FDA's 2021 PMTA final rule and the recent final guidance for conducting TPPI studies. There is an opportunity for the CORESTA PUB subgroup to serve as a source of up-to-date scientific best practices and guidance on the topic.



New Projects

2.0 Nicotine Flux Review

❖ Background

Nicotine flux has been proposed as a metric of abuse liability and which would allow for comparison of nicotine delivery products. Nicotine flux is the rate at which nicotine is emitted or released from a product → the yield per unit time.

❖ **The NWIP aims to identify and review publicly available literature on nicotine flux, including methodologies, data and its role in measuring abuse liability of tobacco and nicotine products.**

❖ Deliverables:

- CORESTA report describing current understanding and research on nicotine flux
- External publication – to be discussed

- ❖ Xavier and I are extremely grateful to the NWIP Leads:

Projects	Leads
PUB-156-NWIP	Dr. Baxter-Wright
PUB-169-NWIP	Dr. Sherwood
PUB-190-NWIP	Dr. Chrea
PUB-273-NWIP	Dr. Giles & Dr. Yuki
PUB-278-NWIP	Dr. Robert Underly

- ❖ New NWIP leads and all the Sub-Group delegates who have contributed to the rich discussions and valuable scientific insights in building the PUB Knowledge Base and
- ❖ CORESTA staff for facilitating our programme of research



Any Questions?

If you have any questions regarding this report and/or want to participate in PUB Sub-Group please contact krishna_prasad@bat.com