



Product Use Behaviour Sub-Group (PUB)

2021 Annual report

Coordinator: Dr Krishna Prasad (BAT)

Secretary/SC Liaison: Dr Xavier Cahours (IMB)

Smoke-Techno Conference (SSPT2021) Online

October 2021





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 Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.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.



Expanding Membership & Renewed Interest

- ❖ Sub-Group has a healthy membership of 48 representatives
- ❖ The membership is spread across 13 different countries and represents 31 CORESTA member organisations

No	Country	Members	Organisations
1	Bulgaria	1	1
2	Canada	3	2
3	China	7	4
4	France	4	2
5	Germany	3	2
6	Japan	2	1
7	Paraguay	2	1
8	Russian Federation	1	1
9	South Korea	2	1
10	Sweden	1	1
11	Switzerland	7	4
12	UK	1	1
13	USA	13	10
	Total	48	31



PUB Sub-Group Meetings 2021

No	Date	Meeting	Time (UK)	Chair
1	04 May 2021	PUB Sub-Group spring meeting	13:00 – 17:00	Dr. K Prasad & Dr. X Cahours
2	04 Oct 2021	PUB Sub-Group fall meeting	14:00 – 17:00	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.

Several other virtual meetings were held by the respective NWIP leaders to progress the projects in addition to CROM task force meetings which will be covered by Christelle Chrea.



Outline: 2021 Activities

1. PUB-156-NWIP: Abuse liability assessment review update - Complete
2. PUB-169-NWIP: VLNC review update – On hold awaiting interim report
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 – Awaiting SME
6. Next steps



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



Article Contents

Abstract

Comments (0)

ACCEPTED MANUSCRIPT

Human Abuse Liability Assessment of Tobacco and Nicotine Products: Approaches for Meeting 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** ▼

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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



Board Guidance & Next Steps

- ❖ Board guidance sought regarding update the VLNC review with appropriately amended timelines, or stop the development in light of new considerations
- ❖ Board felt that the review will add value to the VLNC science, as long as it is factual, showing the strengths of published studies, but also the gaps in the total understanding of the impact
- ❖ Review to be updated to incorporate significant new publications and regulatory developments
- ❖ Narrative being re-worked to highlight remaining knowledge gaps identified in the open literature
- ❖ Target completion date December 2021



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



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.

❖ The full program is expected to be 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 from review team
- Prepare final draft of paper and distribute for review to the scientific commission
- Collect comments from the scientific commission on final draft



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 YYMMDD 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.

Awaiting identification of SME to re-start

- ❖ 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

- ❖ 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	Prof. Capone

- ❖ 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 the PUB Sub-Group
please contact krishna_prasad@bat.com