



# **Product Use Behaviour Sub-Group (PUB)**

## **2018 PUB SG Report**

Coordinator: Dr Krishna Prasad (BAT)

Secretary/ SC Liaison: Dr Xavier Cahours (ITG)

24 October 2018

Kunming, China



# Product Use Behaviour Measurements

- ❖ Existing and emerging regulation for introducing NGPs
- ❖ Number of Product Use Behaviour measurements required:
  - Sensory Experience
  - Level of consumption
  - Puffing Topography
  - Intention to use/quit
  - Ability to understand & comply with ‘use instruction’/ potential misuse
  - Abuse Liability Assessment
  - Perception & Comprehension of NGP ‘modified risk communication’
  - Pattern of use



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 Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.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



## Outline: 2018 Activities

1. TSB-115-NWIP: eCig literature review
2. PUB-155-NWIP: Reference Cigarettes for Human Studies update
3. PUB-156-NWIP: Abuse liability assessment review update
4. PUB-169-NWIP: VLNC review update
5. PUB-182-NWIP: SRNT Commentary update
6. PUB-190-NWIP: Formation of CROM Task Force
7. Knowledge Sharing
8. Next steps



# 1.0 TSB-115-NWIP



## New Work Item Proposal

STDS-002-CCA-C2\_New Work Item Proposal-160520

To be completed by the Proposer

Proposal date (all dates in YYMMDD format):

160529

Proposer (Individual or Working Group)

TSB

Submitted by: (Name, Organization):

Krishna Prasad

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

To be completed by the CORESTA Secretariat

Date Received by Secretariat:

160603

Reference number:

115

Date forwarded to the Scientific Commission

160610

Deadline for answer by Scientific Commission

160624

- Literature review of e-cig use-behaviour studies published in peer reviewed journals to build a comprehensive knowledgebase.
- Use this review to identify gaps in the knowledge and propose relevant studies that the PUB sub-group should initiate to fill the gaps.



# 1.0 TSB-115-NWIP

- Literature review of e-cig use-behaviour studies submitted: 12th June 2018 – accepted: 16th August 2018
- Published in Beiträge zur Tabakforschung International
- Project team set up to address the identified gaps in the knowledge and propose relevant studies



Beiträge zur Tabakforschung International  
Contributions to Tobacco Research  
Volume 28 · No. · August 2018  
DOI: 10.2478/cttr-2018-0009

## A Review of Electronic Cigarette Use Behaviour Studies\*

by

Xavier Cahours<sup>1</sup> and Krishna Prasad<sup>2</sup>

<sup>1</sup> Imperial Brands, Rue Danton, Fleury-Les-Aubrais, 45404, France

<sup>2</sup> British American Tobacco, Regents Park Road, Southampton, SO15 8TL, United Kingdom



## 2.0 PUB-155-NWIP



### New Work Item Proposal

STDS-002-CCA-C2\_New Work Item Proposal-160520

To be completed by the Proposer

<b>Proposal date</b> (all dates in YYMMDD format): 170721
<b>Proposer</b> (Individual or Working Group): PUB
<b>Submitted by:</b> (Name, Organization): Krishna Prasad
<b>On behalf of</b> (Organization, if different from above): CORESTA

To be completed by the CORESTA Secretariat

<b>Date Received by Secretariat:</b> 170721
<b>Reference number:</b> <b>155</b>
<b>Date forwarded to the Scientific Commission</b> 170724
<b>Deadline for answer by Scientific Commission</b> <b>170804</b>

**CANCELLED\***

Develop reference cigarettes similar to Kentucky Reference for use in Human Studies

- The proposed tar yield does not reflect all markets, e.g. US market
- Any new product will require ITP approval for introduction in the US
- For some other markets, an authorization may be needed
- With a reference cigarette that is not users' own brand, a familiarization may be required

\* SC meeting in the US 2018



# 3.0 PUB-156-NWIP



## New Work Item Proposal

STDS-002-CCA-C2\_New Work Item Proposal-170306

To be completed by the Proposer

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

To be completed by the CORESTA Secretariat

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

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.





## 4.0 PUB-169-NWIP

Framework established

1. traditional methods for abuse liability testing
2. attractiveness and product appeal considerations
3. PMTA submissions, feedback and case studies
4. perspective from international jurisdictions (eg: EMA/WHO)

First draft in preparation Q4 2018

Submit manuscript Q2 2019



## 4.0 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 YYYYMMDD 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

### Framework established

1. Does the reduction of nicotine content in cigarettes to a very low level modify cigarette use patterns?
2. Restricted to clinical, behavioural and perceptual studies in Man
3. Limited to studies among current cigarette smokers
  - No studies have been found which examine the effects of VLNC on initiation to cigarette use

Writing team: Mohamadi Sakar (Altria) with the participation of Paul Nelson (RAI), Jeff Smith (RAI), Javier Matinez (JTI), Xavier Cahours (Imperial), Krishna Prasad (BAT) and Neil Sherwood (Independent Consultant)

Final draft in preparation, target: Q4 2018; Submission dates, target: Q2 2019



## 5.0 PUB-182-NWIP



### New Work Item Proposal

STDS-002-CCA-C2\_New Work Item Proposal-170306

To be completed by the Proposer

<b>Proposal date</b> (all dates in YYMMDD format): 180315
<b>Proposer</b> (Individual or Working Group) Product Use Behaviour Sub-Group
<b>Submitted by:</b> (Name, Organization): Xavier Cahours, Krishna Prasad
<b>On behalf of</b> (Organization, if different from above):

To be completed by the CORESTA Secretariat

<b>Date Received by Secretariat:</b> 180315
<b>Reference number:</b> <b>182</b>
<b>Date forwarded to the Scientific Commission</b> 180319
<b>Deadline for answer by Scientific Commission</b> 180329

Present a commentary based on Cahours & Prasad 2018, E-cig review and CORESTA Guide No. 22, for a publication in SRNT journal.

Submitted on 29 August 2018  
Manuscript Id. NTR-2018-305  
Awaiting reviewers comments!



- ❖ How individuals use these products has strong implications for nicotine intake and exposure to other potential toxicants
- ❖ Review reported a wide variations in puff volume, puff duration and inter-puff interval across products, settings, and individuals
- ❖ Puffing regime for regulation is difficult, CORESTA Recommended Method No. 81 lays out the essential requirements
- ❖ The amount of aerosol generated can be influenced by a number of factors, including product design, vaping topography, and device setting as highlighted in the review.
- ❖ Parameters that need to be considered include puff duration, puff volume, puff frequency, puff profile, puff number, battery charge status, coil or atomiser age, voltage setting, ventilation setting, and device orientation.
- ❖ These parameters are not independent and the settings should be based on representative human usage rather than the maximum extremes of each individual parameter.



# 5.0 PUB-182-NWIP

Reply Reply All Forward IM  
Wed 29/08/2018 16:57

**N** Nicotine & Tobacco Research <onbehalf@manuscriptcentral.com>  
Nicotine & Tobacco Research - Manuscript ID NTR-2018-305

To: Krishna Prasad  
Cc: Xavier.CANOURS@fr.ampub.com, Krishna Prasad

[ This is an EXTERNAL email ]

29-Aug-2018

Dear Dr Prasad

Your manuscript entitled "Factors to consider in arriving at a puffing regime to represent intense ENDS use" has been successfully submitted online and is presently being evaluated for consideration for publication in Nicotine & Tobacco Research.

If you have followed the author guidelines in preparing and submitting your manuscript, it will be forwarded to the editors for evaluation. If your manuscript does not comply with the guidelines, you will be asked to bring it into compliance before the manuscript is considered for review.

Your manuscript ID is NTR-2018-305.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne Manuscripts at <https://mc.manuscriptcentral.com/ntr> and edit your user information as appropriate.

You can also view the status of your manuscript at any time by checking your Author Centre after logging in to <https://mc.manuscriptcentral.com/ntr>.

Please note that all future communications concerning this manuscript will be directed to the Corresponding Author only.

Thank you for submitting your manuscript to Nicotine & Tobacco Research.

Yours sincerely,

Margaret Searle  
Managing Editor, Nicotine & Tobacco Research  
Email: [ntr.editorialoffice@oup.com](mailto:ntr.editorialoffice@oup.com)

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Nicotine & Tobacco Research

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- 1 Submitted Manuscripts >
- 1 Manuscripts I Have Co-Authored >
- Start New Submission >
- Legacy Instructions >
- E.Mact.Dorant.E.malle >

## Submitted Manuscripts

STATUS	ID	TITLE	CREATED	SUBMITTED
EO: Searle, Margaret <ul style="list-style-type: none"> <li>• Awaiting Decision</li> <li>• Awaiting Reviewer Scores</li> </ul>	NTR-2018-305	Factors to consider in arriving at a puffing regime to represent intense ENDS use <a href="#" style="color: #0070c0; text-decoration: none;">View Submission</a>	20-Apr-2018	29-Aug-2018



## 5.0 PUB-190-NWIP



### New Work Item Proposal

STDS-002-CCA-C2\_New Work Item Proposal-170306

Development and validation of Consumer Reported Outcome Measures (CROM) for the Global Tobacco Industry using a Consortium approach

*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)**



## 5.0 PUB-190-NWIP

CROM top line objectives:

1. Develop CROM approach for Tobacco and Nicotine Products under guidance of industry, academia and regulatory agency stakeholders
2. Adopt validation guidelines for CROM for use in the assessment of products with reduced risk potential and
3. Create a repository of existing and new CROM instruments outlining measurement and validation approaches

CROM TF set up – introductory meeting held 22 Oct 2018,

- Coordinator, Rapporteur, Working Group members for Phase 0 selected
- Address how CROM would help meet the needs identified in this area

Draft WG report summarising the output - May 2019



- ❖ Perceptions of the relative harm of electronic cigarettes compared with smoking in the USA
- ❖ Review of analytical approaches to assess transitions in patterns of tobacco product use in the population
- ❖ Patterns of use behaviour in a sample of Japanese Heat not Burn Tobacco Product users
- ❖ Characterisation of puffing topography of a prototype electronic cigarette in adult exclusive cigarette smokers and adult exclusive e-cigarette users
- ❖ Tobacco Computational Modelling Meeting NYU College of Global Public Health 23-24 July 2018



## 8.0 Next Steps

No.	Description	Who	When
1	NWIP 115 – <b>Complete</b> e-cig literature review published	XC/KP	Aug 18
2	<del>NWIP 155 – <b>Cancelled</b> Manufacture a 7mg reference Cigarette</del>	-	-
3	NWIP 156 – First draft Abuse Liability paper for review	MK/KP	Feb 19
4	NWIP 169 – VLNC outline agreed first draft for review	NS/KP	Feb 19
5	NWIP 182 – SRNT commentary submitted next steps	XC/KP	TBC
6	NWIP 190 – CROM TF WG1 draft report	CC/KP	May 19
7	Submit Abuse Liability review manuscript for SC approval	KP/XC	Q2 19
8	Submit VLNC review manuscript for SC approval	KP/XC	Q2 19
9	Next meeting Spring 2019 – Montreal, Canada	GG/KP	Q2 19



**Any Questions?**