



# **Product Use Behaviour Sub-Group (PUB) 2020 Annual report**

Coordinator: Dr Krishna Prasad (BAT)

Secretary/ SC Liaison: Dr Xavier Cahours (IMB)

October 2020

CORESTA Congress, Online



# 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 Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.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 52 representatives
- ❖ The membership is spread across 11 different countries and represents 32 CORESTA member organisations

No	Country	Members	Organisations
1	Canada	4	2
2	China	5	4
3	France	3	2
4	Germany	5	4
5	Japan	3	1
6	Paraguay	2	1
7	South Korea	2	1
8	Sweden	2	1
9	Switzerland	8	5
10	UK	3	2
11	USA	15	9
	<b>Total</b>	<b>52</b>	<b>32</b>



# PUB Spring Meetings 2020

No	Date	Meeting	Time (UK)	Chair
1	23 April 2020	Human Abuse Liability (HAL) Review	16:00 – 17:00	Dr. Sarah Baxter-Wright
2	28 April 2020	VLNC Review	16:00 – 17:00	Dr. Neil Sherwood
3	30 April 2020	Standards for Connected ENDS	16:00 – 17:00	Dr. Michael Joseph Capone
4	04 May 2020	PUB Sub-Group meeting	14:00 – 17:00	Dr. K Prasad & Dr. X 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.

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



# Outline: 2020 Activities

1. Proposals to fill gaps identified by e-cig use behaviour review
2. PUB-156-NWIP: Abuse liability assessment review update
3. PUB-169-NWIP: VLNC review update
4. PUB-190-NWIP: Formation of CROM Task Force
5. New Areas of Research
6. Next steps



# 1.0 Proposals to fill gaps

1. Vaping topography comparison of populations / sub-populations
2. Vaping topography of different Device type
3. Puffing topography of HTPs: comparison of populations / sub-populations and puffing topography of different HTPs

## **It was agreed to proceed in the following order:**

1. Appoint study leaders to collate & report data
2. Identify unpublished studies among members
3. Provide a framework for possible publication
4. Identify gaps and propose studies to fill gaps

**A3 (action)** Dai and Sarah were asked to present some data to the Sub-Group at the next meeting



## 2.0 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.



# Writing Committee

- **Sarah Baxter Wright**      **RAI Services**
- **Andrea Vansickel**      **Altria**
- **Leanne Campbell**      **RAI Services**
- **Neil Sherwood**      **Independent Consultant**
- **Michael Kong**      **Altasciences Clinical Research**
- **Sarah Evans**      **Turning Point Brands**
  
- **Krishna Prasad**      **BAT– Co-Ordinator PUB Sub-Group**
- **Xavier Cahours**      **IMB – Secretary PUB Sub-Group**





## Update - Next Steps

- A10 Review abstracts for CORESTA and TSRC 2020, prepared, submitted and accepted.
- A11 Above abstracts reviewed and approved by CORESTA SC prior to submission
- A12 NWIP being prepared for 'HAL Guidelines' for approval by SC after the next meeting (*Oct 2020*).
- A13 Names from the CTP sought to join the PUB-SG and potentially participate in the NWIP activities above – *XC (Oct 2020)*.

**Final HAL Review manuscript approved by the CORESTA SC and Board, awaiting participating member company internal approval for submission.**



## 3.0 PUB-169-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): 170922
<b>Proposer</b> (Individual or Working Group) Product Use Behaviour Subgroup
<b>Submitted by:</b> (Name, Organization): Mohamadi Sarkar, ALCS
<b>On behalf of</b> (Organization, if different from above): Product Use Behaviour Subgroup

To be completed by the CORESTA Secretariat

<b>Date Received by Secretariat:</b> 171023
<b>Reference number:</b> <b>169</b>
<b>Date forwarded to the Scientific Commission</b> 171117
<b>Deadline for answer by Scientific Commission</b> 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



# Writing Committee

- **Neil Sherwood** Independent Consultant
- **Mohamadi Sakar** Altria Client Services
- **Paul Nelson** RAI Services
- **Jeff Smith** RAI Services
- **Javier Matinez / Kelli Sayers** JTI
  
- **Krishna Prasad** BAT - Co-Ordinator PUB Sub-Group
- **Xavier Cahours** IMB – Secretary PUB Sub-Group

- ❖ Protocol for systematic review of literature up to end 2018 developed
- ❖ Search conducted and database (~ 300 papers) compiled
- ❖ Relevant papers identified through an initial screen using I/E criteria based on abstracts and titles (~ 170 papers)
- ❖ Key papers to be included by screening based on I/E criteria and relevance (~ 80 papers)
- ❖ Consensus narrative developed

- ❖ The proliferation of new studies (e.g. N&TR Supplement December 2019) which have introduced alternative endpoints and success criteria (e.g. dual use)
- ❖ US FDA CTP approval of PMTA for 22<sup>nd</sup> Century Group Moonlight™ cigarettes, “...*the first product to successfully demonstrate the potential for these types of tobacco products to help reduce nicotine dependence among addicted smokers...*” (Zeller, 2019)
- ❖ US FDA CTP TPSAC review of MRTPA for 22<sup>nd</sup> Century Group VLN™ cigarettes, promoting the argument that results should be interpreted under an assumed VLNC cigarette only market
- ❖ Further development of a nicotine reduction policy has been delayed in the U.S. and is currently not an issue with major visibility in other markets



# 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 to be re-worked to highlight remaining knowledge gaps identified in the open literature
- ❖ Target completion date December 2020



## 4.0 PUB-190-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 YYYYMMDD format): 180503
<b>Proposer</b> (Individual or Working Group) Krishna Prasad, PUB Coordinator
<b>Submitted by:</b> (Name, Organization): Krishna Prasad, BAT
<b>On behalf of</b> (Organization, if different from above):

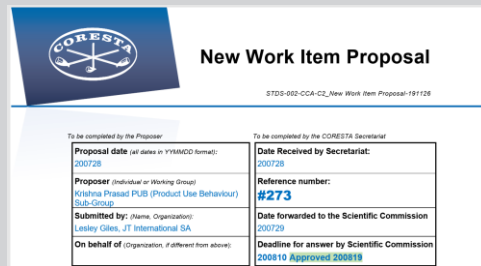
To be completed by the CORESTA Secretariat

<b>Date Received by Secretariat:</b> 180529
<b>Reference number:</b> <b>190</b>
<b>Date forwarded to the Scientific Commission</b> 180530
<b>Deadline for answer by Scientific Commission</b> <b>180607 (SC meeting)</b>

- 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 Scientific Commission and the Board
- Going forward the TF activities will be covered separately

# 5.0 New Areas of Research

No	NWIP	Topics
1	Dr Capone	Best practice technical guide for data generated by connected ENDS
2	Dr Ljung	Oral tobacco & nicotine product definitions to support harmonisation of nomenclature
3	Dr Giles	Expand use behaviour terms to include emerging product platforms
4	Dr Baxter-Wright	Technical guidelines to address HAL & Use Behaviour studies
5	Dr Yuki	Collate unpublished THP use behaviour studies conducted by members



**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
<b>Proposal date</b> (if date in YYYYMM format): 200728	<b>Date Received by Secretariat:</b> 200728
<b>Proposer</b> (Individual or Working Group) Krishna Prasad PUB (Product Use Behaviour) Sub-Group	<b>Reference number:</b> #273
<b>Submitted by:</b> (Name, Organisation) Lesley Giles, JT International SA	<b>Date forwarded to the Scientific Commission</b> 200729
<b>On behalf of:</b> (Organisation, if different from above)	<b>Deadline for answer by Scientific Commission</b> 200810 Approved 200819

NWIP 273 has been created and approved to collate and define tobacco and nicotine products and their use behaviour terms covering the areas 2 and 3 above. This project will be led by Dr Lesley Giles from JTI, Switzerland.

❖ Fall 2020 PUB Sub-Group virtual meeting will be held on 06 October 2020





## Any Questions?

A huge **thank you** to all the members for their contribution through out the year.

If you have any questions regarding this report and/or want to participate in PUB Sub-Group please contact [krishna\\_prasad@bat.com](mailto:krishna_prasad@bat.com)