



Product Use Behaviour Sub-Group (PUB)

2017 Annual Report

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Product Use Behaviour Measurements

- ❖ Benefit of introducing Modified Risk Tobacco Product
- ❖ 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 Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.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: 2017 Activities

1. Puffing Topography Inter-lab Study Report
2. TSB-115-NWIP: eCig literature review
3. PUB-155-NWIP: Reference Cigarettes for Human Studies update
4. PUB-156-NWIP: Abuse liability assessment update
5. Reduced nicotine content cigarette review
6. Instruments for Behavioural Research
7. Population Modelling
8. Next steps



1.0 Inter-lab Study Technical Report

REPORTS **current**

Puffing Topography Inter-lab Study

TSB Technical Report

January 2017

The CORESTA Smoking Behaviour Sub-Group conducted a study to determine if various human puffing topography devices deliver comparable results for puff volume and puff duration. Commercial and proprietary smoking topography instruments have been available and used for many years but there is limited information regarding validation of instruments used. The study measures puff volume and puff duration with four different types of human topography devices, using two commercial cigarettes that represent the low and higher end pressure drops (PD) of commercial products. The data collected was used to determine the accuracy of each device.



2.0 TSB-115-NWIP: eCig Literature Review

❖ Purpose

- E-cigarette use is significantly different compared to smoking, however, very limited information is available on topography and subjective effects of e-cigarettes.
- All relevant e-cig use-behaviour studies published in peer reviewed journals, will be considered to produce a comprehensive knowledgebase.
- This will form the basis for identifying gaps and suggest relevant studies that TSB should initiate

2.0 TSB-115-NWIP: eCig Literature Review

- ❖ **TSB-115-DTR-[Review of e-cig use-behaviour studies] -161001**
 - **Literature search done:**
 - keywords: e-cigarette or vaping AND prevalence/consumption/pattern/reason for use/behaviour/topography).
 - Extraction of key publications (n= 175)
 - Analysis of the most relevant (n= 45)
 - **First draft literature review completed & discussed**
 - **Writing committee review planned for Q4 2017**
 - **Manuscript will be sent for SC approval early 2018**



3.0 PUB-155-NWIP: Reference Cigarette

❖ Background

- Reference cigarettes play an important role in the identification and assessment of cigarette smoke-related effects
- To date reference cigarettes have been designed for chemical and biological (*in vitro*) assessment methodology
- There is a requirement for developing similar reference cigarettes that can be used in Human Studies

❖ Purpose

- Develop reference cigarettes that can be used as a comparator in Human Studies for assessment of cigarette smoke-related effects



3.0 PUB-155-NWIP: Reference Cigarette

❖ Status Update

- Analysis of representative end-market/regional cigarette data reviewed at global level to arrive at most common yield
- Most common yields of next generation tobacco & nicotine products examined
- First step: 6mg 'tar', US blend, LIP paper, commercial cigarette proposed to be manufactured in Europe
- Detailed product info available on website for regulator (and the public)
- Product volume: 200,000 sticks; packed at 20 per pack
- Product will be taxed for ease of transfer outside EU



3.0 PUB-155-NWIP: Reference Cigarette

❖ Challenges/Limitations

- 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
- University of Kentucky will be approached to help 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

❖ Next Steps

- Proposal will be escalated to the SC for approval



4.0 PUB-156-NWIP: Abuse Liability Assessment

❖ Background

- MRTPA guidelines recommend human studies to assess abuse liability compared to other tobacco products
- Likelihood that individuals will develop physical and/or psychological dependence on the tobacco product (USDHHS 2012)
- There is a requirement for developing a better understanding of assessing the abuse liability of tobacco & nicotine products

❖ Purpose

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



4.0 PUB-156-NWIP: Abuse Liability Assessment

❖ Status Update

- Outline of the review to include - current regulatory demands for abuse liability assessment (ALA) for PMTA/MRTP
- Current ALA assessments used in drug development and relevance to tobacco products
- Attractiveness/Addictiveness Model
- Challenges with assessing ALA in tobacco products

❖ Next steps

- Draft underway, writing committee being assembled to assist in review
- First draft for review – Sept 2018

5.0 Reduced Nicotine Content Cigarettes

- ❖ Previous attempt to review the science of reduced nicotine cigarette discontinued due to staff movement and lack of sponsor support
- ❖ Recent FDA announcement to pursue lowering nicotine in cigarettes to non-addictive levels has highlighted the need to review the science
 - VLNC cigarettes produce reduced exposure to nicotine, reduced smoking and reduced dependence
 - much is still unknown, including the effects on risk perception and behaviour

5.0 Reduced Nicotine Content Cigarettes

- ❖ Propose reviewing the current evidence on nicotine reduction and discuss some of the challenges
- ❖ Scope to include:
 1. clinical output and limitations
 2. user satisfaction and behaviour
 3. non-user risk perception of very low nicotine cigarettes (VLNC)
- ❖ Summarize the current knowledge on the effect of VLNC on consumers and non-consumers
- ❖ Identify the gaps and suggest potential studies



6.0 Instruments for Behaviour Research

External expertise sought to address the development and validation of instruments for behaviour research

MAPI Research Trust has proposed - Consortium approach

❖ Overarching goals for the consortium:

- Adapt existing international standards for creation, validation, translation and application of questionnaire instruments used to describe consumer reported outcome measures (CROM) with reduced risk products and comparators (e.g., conventional tobacco products, NRTs).
- Creation of a repository of existing and new CROM outlining measurement properties and applications.

6.0 Instruments for Behaviour Research

- Guidelines on CROM development, adaptation, application and analysis and interpretation of results in accordance with adapted CROM standards

❖ Next Steps

- Identification of key stakeholders from the industry, academia and regulatory agencies who could provide expertise and guidance in CROM development and Tobacco and Nicotine Product applications focusing on some key domains (product use behaviour, dependence, product transition, health outcomes, quality of life) and on post-marketing surveillance
- Development of consortium membership and work plan including structure, governance, by laws

❖ Subject to CORESTA Scientific Commission recommendation and Board approval



7.0 Population Modelling

- ❖ PUB sub-group to identify SME from member companies
- ❖ SMEs will be encouraged to hold a workshop to propose next steps



8.0 Next Steps

No.	Description	Who	When
1	NWIP 115 – Complete e-cig literature review 2 nd round	XC/WC	Jan 18
2	NWIP 155 – Manufacture a 7mg reference Cigarette	KP/WC	Jul 18
3	NWIP 156 – Draft Abuse Liability paper for review	MK/WC	Feb 18
4	Propose NWIP on Reduced Nicotine Cigarette review	MS/KP	Dec 17
5	Seek CORESTA approval for Consortium approach	KP/SC	Jan 18
6	Identify SME to lead Population Modelling	ALL	Apr 18
7	Submit for e-cig review manuscript SC approval	KP/XC	Apr 18
8	Submit for e-cig review manuscript for publication	KP/XC	Jun 18
9	Next meeting Spring 2018 – TBD	KP/GP	Q1 '18



Any Questions?