



Smoking Behaviour Sub-Group (TSB)

2016 Annual Report

Coordinator: Dr Krishna Prasad (BAT)

Secretary: Dr Xavier Cahours (ITG)

SC Liaison: Dr Martin Blumenstock (BAT)

11 October 2016

Berlin, Germany



TSB 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 Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.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: 2016 Activities

1. CRM80: Part filter method
 2. Topography device comparison study
 3. Modified holders for eCig Topography Devices
 4. NWIP115 – eCig literature review
 5. Abuse liability assessment update
 6. Reduced nicotine content cigarette review
 7. Reference Cigarettes for Human Studies
 8. Consumer Risk Perception
- ❖ Next steps



1.0 CRM 80: Part Filter Method

RECOMMENDED METHODS

No. 80 - Use of the Part-Filter Method for the Estimation of Smokers' Exposure to Nicotine and Nicotine-Free Dry Particulate Matter

January 2016

- ❖ Following successful completion of three ring trials in 2012, 2013 & 2014, all the learnings were compiled and included in the CORESTA recommended method.
- ❖ CRM 80 was approved by the Board in January 2016 and is accessible to the members via CORESTA website.



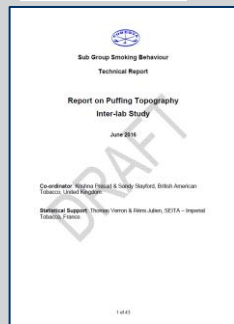
2.0 Topography Device Collaborative Study

- ❖ Puff volume and puff duration measurements made using multiple units of four different topography devices were analysed to determine the uncertainty associated with laboratories and smoking topography devices.
 - Intra lab*device coefficient of variations ranged from 4% to 12%
 - Inter lab*device coefficient of variations ranged from 10% to 26%
 - Both intra and inter lab*device variabilities change non linearly with average flow rate

2.0 Topography Device Collaborative Study Report Update



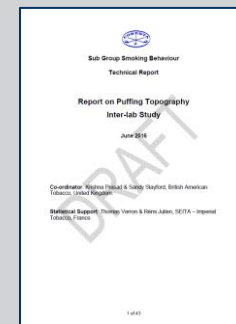
Assess the outlier detection impact by changing the P-Value of Cochran test (e.g. 10%) in order to take into account more data in the computation of r^* and R^*



Reviewing



Modifications



Outlier' Alternatives

Presentation of the main modifications



2.0 Topography Device Collaborative Study Next Steps

- ❖ Issue report for SC approval - October '16
- ❖ Agree publication - October '16
- ❖ Draft Manuscript – March '17
- ❖ Review & submit for publication June '17

3.0 Modified e-cig topography holders

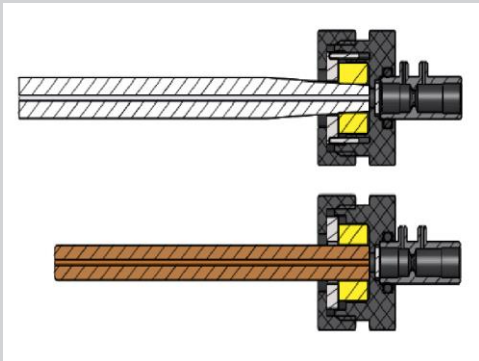
- ❖ **Issue1:** e-cigarette aerosol exits through a hole which is smaller than the orifice, resulting in erroneous pressure differential measurement
- ❖ **Challenge:** create a pressure differential through the orifice without perturbing the user behaviour
- ❖ **Solution:** disturb the flow in order to create a pressure differential across the orifice in the cigarette-holder

Orifice with a bar chosen as it is simple and easier to manufacture



3.0 Modified e-cig topography holders

- ❖ **Issue2:** e-cigarette mouth piece come in all shapes and sizes
- ❖ **Challenge:** connect these e-cigarette mouth pieces to the topography device holder without leakage
- ❖ **Solution:** adaptor with elastomer seals developed to accommodate various shapes and sizes of e-cigarette mouth-ends



4.0 Review of e-cig use-behaviour studies

- ❖ NWIP-115-[Review of e-cig use-behaviour studies] -161001
 - 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

4.0 Review of e-cig use-behaviour studies

- ❖ **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 2016**
 - **Manuscript will be sent for SC approval early 2017**



5.0 Addictiveness & Attractiveness Update

- ❖ TSB is charged with keeping a watching brief on this topic, Dr Lesley Giles has agreed to keep the sub-group updated on this topic.

- ❖ Two external presentations shared
 1. “Addictiveness” - Measures and Methods by Dr Neil Sherwood
 2. Human Abuse Potential and Tobacco Products - Applying Experience with Drugs to Tobacco Products by Dr Graham Wood

- ❖ TSB agreed to prepare a Abuse Liability Assessment (ALA) review proposal lead by Dr Graham Wood



6.0 Reduced Nicotine Content manuscript

Three key areas of literature identified (total of ~30 papers):

1. Clinical trials where effects of reduced nicotine cigarettes (either in an acute or chronic setting) are investigated in smoking volunteers who switch from their usual brand
2. Smoking cessation trials where the effects of reduced nicotine cigarettes on smoking cessation rates are investigated typically in conjunction with NRT products
3. Commentaries, editorials and reviews on the relative benefits/drawbacks of the nicotine reduction theory

First draft review will be available December 2016



7.0 Reference Cigarettes for Human Studies

- ❖ Debate & discuss the need for reference cigarettes for Human Studies
- ❖ Agree the suitable product characteristics for the design of such reference products
- ❖ Approach based on analysis of representative end-market/regional product data at global level and most common yields of next generation tobacco & nicotine products
- ❖ Two blends (US Blend and Virginia) at two tar levels 10 & 7 mg proposed – needs further/wider discussion

8.0 Consumer Risk Perception

- ❖ Scientific studies assessing consumer beliefs about health risks – MRTTP draft guide lines 2012
- ❖ Importance of conceptually sound, reliable & valid measures highlighted – Guidance on Patient Reported Outcome measures 2009
- ❖ Three phase methodological approach taken to develop the Perceived Risk Instrument (PRI)
- ❖ PRI – Perceived Health risks (18 items), Addiction risks (7 items) and Harm to others (2 items)
- ❖ Validated PRI available to use via MAPI PROinformation@mapi-trust.org



Next Steps

No.	Description	Who	When
1	Topography Device Comparison study report for SC approval	KP/TV	Oct 16
2	NWIP 115 – Complete writing committee e-cig literature review	KP/WC	Dec 16
3	Draft Reduced Nicotine Cigarette review for TSB discussion	LG	Dec 16
4	Circulate RNC review to the writing committee	KP	Jan 17
5	Further discuss Human Studies Reference Cigarette proposal	MB/SC	Apr 17
6	Propose and discuss next steps for Consumer Risk Perception	CC	Apr 17
7	Discuss outline for proposal for ALA review	GW	Apr 17
8	Prepare NWIPs for SC consideration	KP/TSB	May 17
9	Review & submit for publication Topography manuscript	KP/TV	Jun 17

Expand the activities of the SG to examine non-competitive scientific methodology issues:

- ❖ Consumer Risk Perception
- ❖ Abuse Liability Assessment
- ❖ Use behaviour to predict transitions / Post market surveillance
- ❖ Modelling population health impact



Any Questions?



Smoking Behaviour Sub-Group (TSB)

- ❖ Group originally set up as a committee reporting directly to the Scientific Commission, then became a Sub Group in 1996
- ❖ Typically meeting twice a year
- ❖ Tobacco & puffing topography device manufacturers; contract research, quality control & government laboratories; publisher and research institutes participate in collaborative studies
- ❖ Executives:
 - Coordinator: Dr Krishna Prasad (BAT)
 - Secretary: Dr Xavier Cahours (ITG)
 - SC Liaison: Dr Martin Blumenstock (BAT)

- ❖ Abuse liability assessment (ALA) is a validated approach to testing pharmaceutical products, but has not been applied extensively to tobacco products.
- ❖ ALA is a feasible option for tobacco products, however challenges include:
 - diversity of products
 - complexity of products
 - use of ingredients
 - absence of satisfactory placebo products