



CORESTA Biomarkers Sub-Group

A platform for scientific collaboration on tobacco-related biomarkers

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Biomarkers Sub-Group

FDA/CTP Workshop: Biomarkers of Potential Harm

Silver Spring, MD – April 4-5, 2016



CORESTA

Centre de
COopération pour les **RE**cherches **S**cientifiques
Relatives au **T**Abac

Cooperation Centre for Scientific Research Relative to Tobacco



**To be recognised by our members
and relevant external bodies
as an authoritative source of publically available,
credible science and best practices
related to tobacco and its derived products.**



The Purpose of CORESTA

Encourage international cooperation
to actively work
on tobacco-related areas of research



2 x 2 Study Groups

❖ Agronomy & Leaf Integrity

❖ Phytopathology & Genetics

- Agronomy & Breeding
- Curing
- Sustainability
- Pests & plant diseases
- Agrochemical issues
- Good Agricultural Practices

Agro-Phyto

« AP »

❖ Smoke Science

❖ Product Technology

- Technical specifications
- Smoke analysis
- Analytical methods
- Consumer behaviour
- Biomarkers
- In Vitro Toxicity

Smoke-Techno

« SSPT »



Biomarkers Sub-Group

Biomarker Sub-Group

- ❖ Meets two times per year (typically in May and October)
- ❖ Convener: Dr. G.L. Prasad, Ph.D. (RAIS)
- ❖ Secretary: Dr. Kirk Newland, Ph.D. (Celerion)
- ❖ Participants: ~30 delegates from industry, bioanalytical labs, and other organizations



Biomarkers Subgroup Objectives

❖ Objective 1:

To review present knowledge of tobacco and smoking-related biomarkers of exposure and effect, and to document these in meeting minutes, CORESTA reports and scientific publications where appropriate.

❖ Examples include

- Selection, validation and quantification of biomarkers of effect
- Optimization of mass spectrometric methods for biomarker analysis
- Clinical study results
- Applications of systems biology approaches
- Physiological measures as biomarkers of COPD onset
- Published on urinary biomarkers of tobacco exposure and fit-for-purpose approach and smoking behaviour



Biomarkers Subgroup Objectives

❖ Objective 2:

To undertake ring trials / proficiency tests for selected biomarkers

- **Nicotine and metabolite ring trials**
- **Completed proficiency testing of 3-HPMA (publication planned)**
- **NNAL inter-lab method comparison**
 - Welcome participation from non-members of the Sub-Group
 - Study planned for summer 2016



Biomarkers Subgroup Objectives

❖ Objective 3:

To source and develop reference materials to support biomarker analysis for those biomarkers selected for ring trials / proficiency tests

- Discussion on whether a guideline on standards for reference materials could be developed and presented to CORESTA



Biomarkers Sub-Group On-Going Work

- ❖ **Technical Report - Proficiency Test**
3-HPMA Interlaboratory Comparison Study
- ❖ **Technical Report - Proficiency Test**
Comparison BM / NNN-NNK
- ❖ **Technical Report - Proficiency Test**
Ranking of biomarkers in view of prioritisation
- ❖ **Guideline for Reference Standards**



Value of CORESTA

- ❖ **Global interdisciplinary expertise from different sectors**
- ❖ **Focus on advancing scientific knowledge**
- ❖ **Leadership and coordination of inter-lab studies to recommend analytical methods**



More Information

❖ **For more information, please contact:
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Thank you