



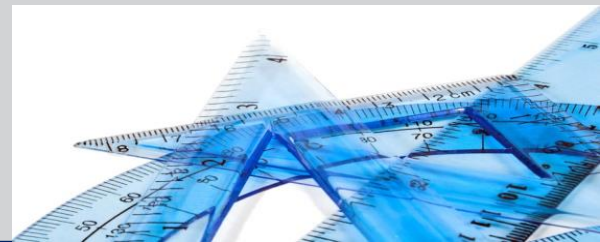
# Cigarette Variability Task Force: CVAR

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- **Secretary and Study Coordinator: Rana Tayyarah**
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- **Statistical Analysis: Michael Morton**
  - Altria Client Services LLC, Richmond VA

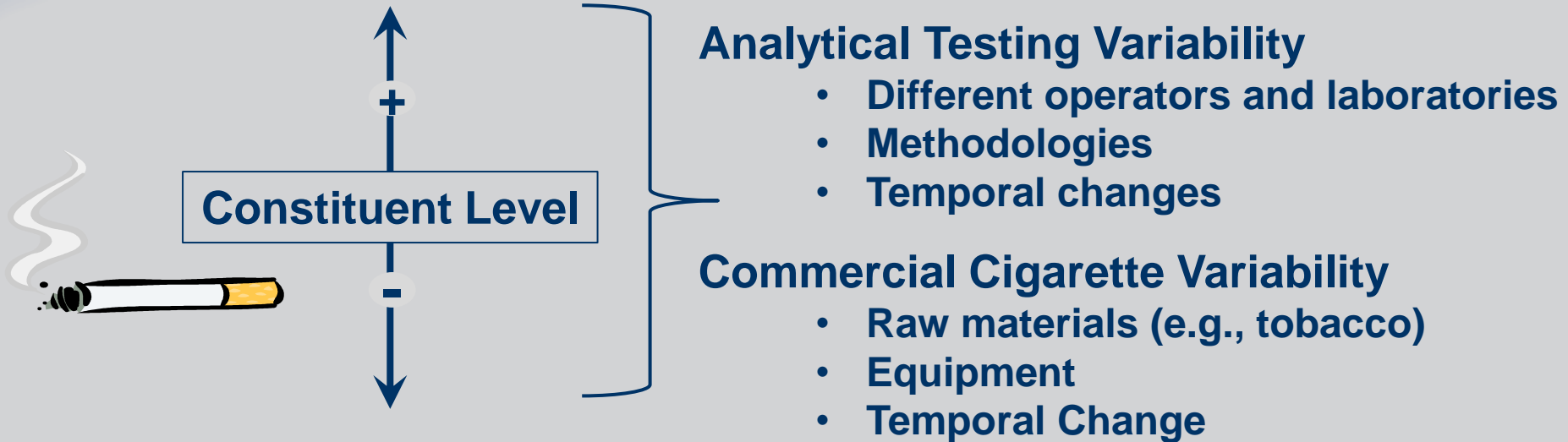
**CORESTA Congress - Berlin Germany  
October 10, 2016**

- ❖ **Scientists measure tobacco and smoke constituents for a variety of reasons**
- ❖ **There is variability associated with measuring these constituents\***
- ❖ **In order for the scientific community to make science-based decisions regarding tobacco and smoke constituents, they need to fully understand this variability**

**\*ISO 8243**



## ❖ Tobacco and smoke analyte variability results from multiple sources:



- ❖ **Generally, analytes present in a higher concentration have lower variability than lower concentration analytes**
- ❖ **Generally, standardized methods show lower variability (e.g., tar, nicotine, CO, and TSNAs)**





# **Cigarette Variability (CVAR) Task Force Objectives**

- 1. To develop an appropriate experimental plan to explore commercial cigarette variability**
- 2. To conduct a collaborative study to enhance the understanding of overall tobacco and smoke analyte variability relevant to commercial cigarette design features**
- 3. To create a CORESTA technical report**

❖ The objective is to conduct a study to understand commercial cigarette variability as determined by the measurement of select tobacco and mainstream smoke analytes

- Physicals and TNCO
- WHO priority list
- Abbreviated US FDA harmful and potentially harmful constituents (HPHC) list
- Hydrogen cyanide (HCN)

Measurement Type	Analyte Class	Measure/Analyte	
<b>Physicals</b>		Pack moisture (as packed)	
		Cigarette weight (as packed)	
		Cigarette weight (post conditioning)	
		Filler/tobacco Weight (post conditioning)	
		Filter Tip Ventilation	
		Circumference	
		Length	
		Resistance to Draw (Open/Closed)	
		Paper porosity	
	<b>Filler<sup>10</sup></b>	Alkaloids	Nicotine
TSNAs		NNN	
		NNK	
		Ammonia	Ammonia (Reported as NH <sub>3</sub> )
Metals		Arsenic	
		Cadmium	
<b>Smoke</b>		TNCO	TPM
	Nicotine		
	Water		
	Carbon Monoxide		
	NFDPM ("tar")		
	Carbonyls		Acetaldehyde
			Acrolein
			Crotonaldehyde
			Formaldehyde
	Volatiles		Acrylonitrile
		Benzene	
		1,3-Butadiene	
		Isoprene	
		Toluene	
		Ammonia	Ammonia
		PAA	4-Aminobiphenyl
	1-Aminonaphthalene		
	2-Aminonaphthalene		
	PAH	Benzo[a]pyrene	
		TSNA	NNN
			NNK
		HCN	HCN



# CVAR Study Plan Summary

- ❖ **Analytical testing variability is minimized by:**
  - Tested at one time (ISO and HC)
  - Single laboratory per constituent
  - Statistically balanced run order
  - Reference products (3R4F or 1R6F)
- ❖ **Samples are stored at -20°C to -24°C until time of testing to minimize product changes over time**
- ❖ **The study is designed to allow the estimation of short-term, medium-term, and long-term variability for a range of cigarette types available across the world-wide market**

## ❖ CVAR TF has designed and initiated 3 study phases

1) Phase 1 (short-term variability):  
3 collections within 1 week



Year 1



2) Phase 2 (medium-term variability) – product collected  
each quarter



3) Phase 3 (long-term variability) – product collected beginning of each year  
for 3 years

Year 2



Year 3







# Volunteers

## Commercial Cigarettes

- ❖ Altria Client Services
- ❖ Beijing Cigarette Factory, CNTC
- ❖ British American Tobacco (Germany) GmbH
- ❖ China Tobacco Hunan Industrial Co., Ltd., CNTC
- ❖ Imperial Tobacco Group
- ❖ Japan Tobacco Inc.
- ❖ JT International
- ❖ Philip Morris Int.
- ❖ RAI Services Company



# Volunteers Laboratory Testing

- ❖ Altria Client Services
- ❖ British American Tobacco (Germany) GmbH
- ❖ China Tobacco Anhui Industrial Co., Ltd.
- ❖ China Tobacco Hunan Industrial Co., Ltd., CNTC
- ❖ Imperial Tobacco Group
- ❖ Japan Tobacco Inc.
- ❖ JT International
- ❖ JTI Research & Development, Okolab
- ❖ Liggett Group LLC
- ❖ ITG Brands, LLC
- ❖ RAI Services Company



# CVAR Accomplishments

- ❖ **Phase 1 - Short-term variability:**
  - **Sample collection and analysis is complete**
- ❖ **Phase 2 – Mid-term variability**
  - **Sample collection is complete**
  - **Sample analysis is in progress**
- ❖ **Phase 3 - Long-term variability**
  - **Sample collection will be complete in June 2017**
- ❖ **Technical reports**
  - **Will be published on the CORESTA Web Site**



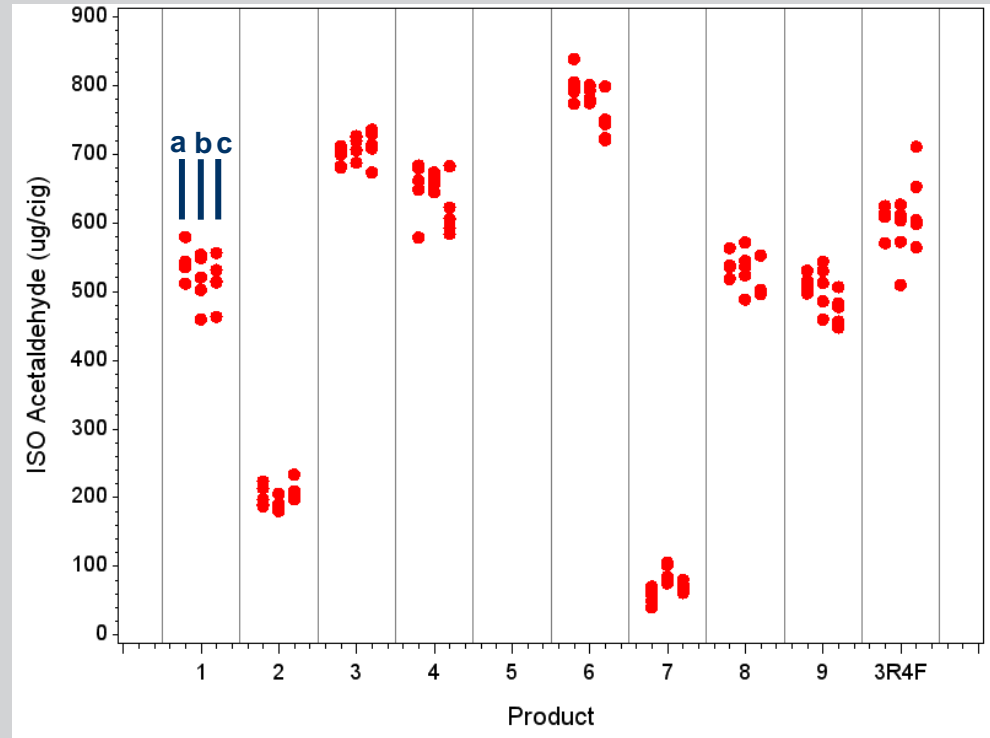
# Summary of Phase 1: Short-term Variability

- ❖ **8 commercial cigarette products + 3R4F and 8 volunteer laboratories**
- ❖ **3 sample times for each commercial product (within 1 weeks time span)**
- ❖ **TNCO measured at all participating labs to evaluate sample-to-sample vs. lab-to-lab variation**
- ❖ **All other measurements were conducted in a single lab**
  - **19 smoke constituents (18 from the FDA and WHO lists + HCN) and Two smoking regimens ( ISO and CI)**
  - **6 filler constituents from the FDA and WHO lists**
  - **Physical measurements**
- ❖ **Sample reps were “interleaved” so that lab drift would not be confounded with sample differences**

# Observations from Phase 1: Short-term Variability

❖ **Smoke constituent analysis conducted on all 10 test products at a single laboratory**

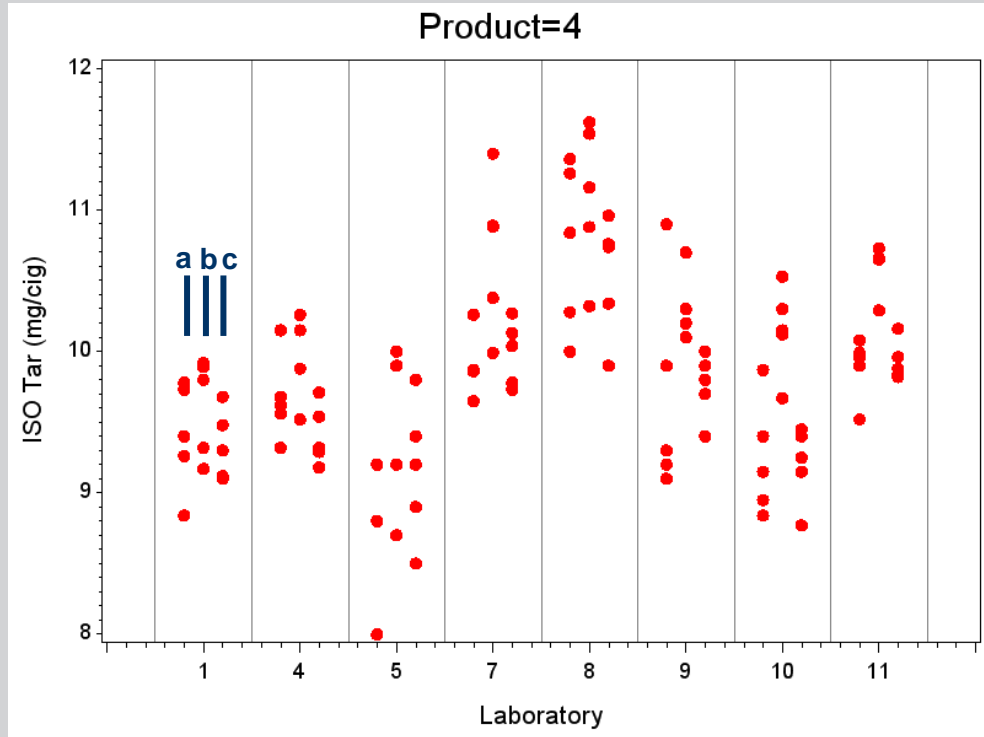
- **Example: Acetaldehyde measured under ISO conditions for all products collected at 3 times within 1 week**
- **Short-term variability is not typically large**



# Observations from Phase 1: Short-term Variability

## ❖ TNCO measured at all 8 participating labs

- Example: Tar measured under ISO conditions (n=5) for product #4 collected at 3 times within 1 week
- Lab-to-Lab variation is the largest component of variation



Product 4 is a medium ventilation product (~20-30%)



# Observations from Phase 1: Short-term Variability

- ❖ For short-term variability (collected within 1 week), sample-to-sample variations are typically small
- ❖ The sample-to-sample variations were similar to repeat testing of 3R4F
- ❖ For TNCO, the sample-to-sample variation were much smaller than lab-to-lab variation

- ❖ **Draft technical report(s) for Phase 1 and 2 will be finalized at the spring CVAR Task Force meeting**
- ❖ **Technical report(s) will then be reviewed by the Scientific Commission and published on the CORESTA website**
- ❖ **Final Phase 3 (long-term variability) samples will be collected in June 2017**
- ❖ **Completion of Phase 3 technical report is planned for 1 qtr 2018**