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# **Presentation to the FDA Risk Communication Advisory Committee and TPSAC joint meeting, August 15<sup>th</sup>, 2013**

Christopher J Proctor, Christopher J  
Shepperd, Nik Newland, Ermioni  
Papadopoulou



# Study Primary Objectives



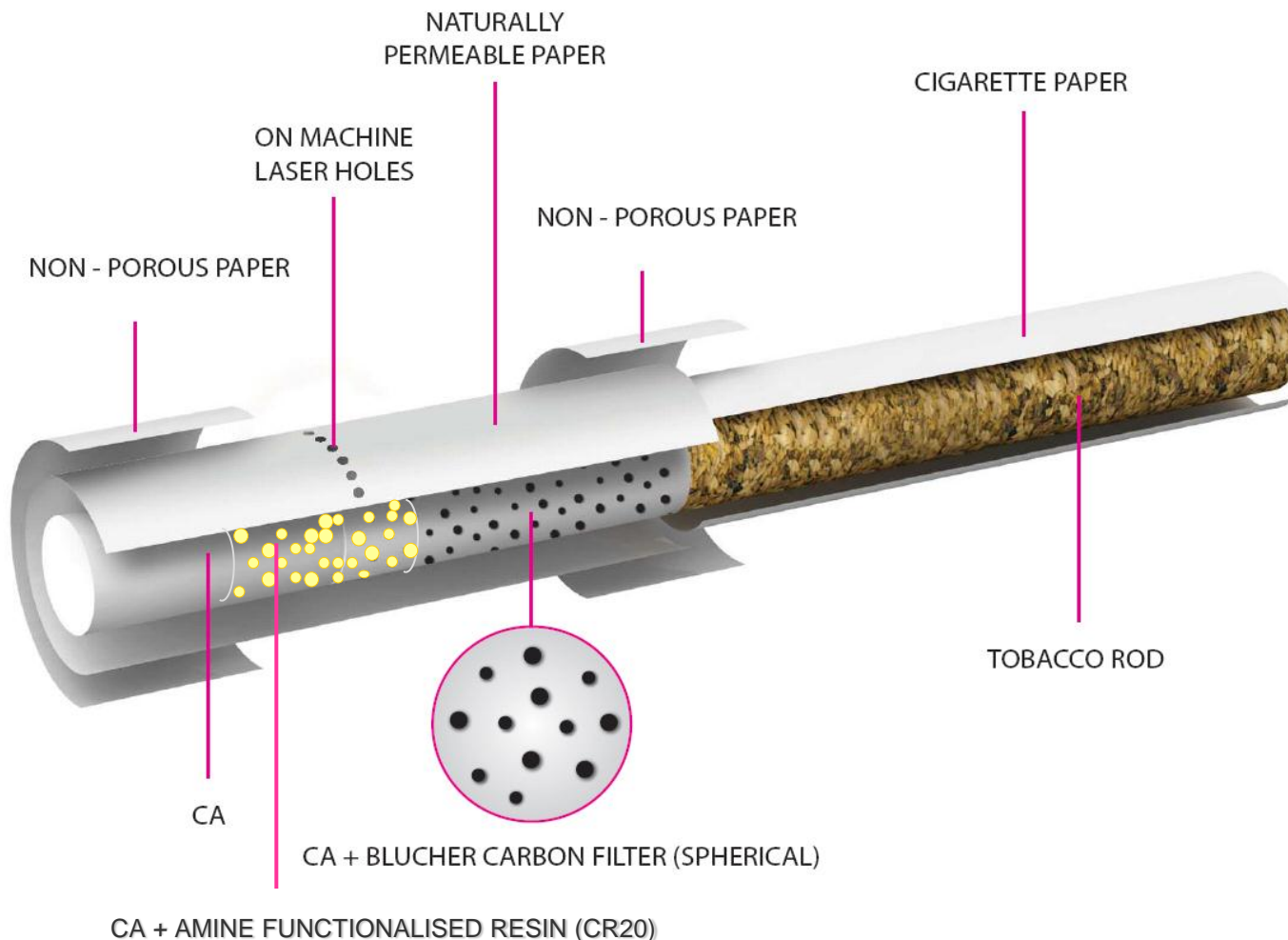
*To descriptively assess within-participant and between-group changes in the identified primary endpoints [Biomarkers of Exposure and Biomarkers of Biological Effect] following a forced switch from a commercial control cigarette to a combustible reduced toxicant prototype (RTP) cigarette of equivalent ISO tar yield.*

Trial Registered in the Current Controlled Trials database, registration number ISRCTN81286286

Protocol published: Shepperd *et al.*: A single-blinded, single-centre, controlled study in healthy adult smokers to identify the effects of a reduced toxicant prototype cigarette on biomarkers of exposure and of biological effects versus commercial cigarettes. *BMC Public Health* 2013 13:690

# Test and Control Products

## Test Product:



## Control product:

Un-branded conventional king size cigarette with cork tipping.

A second version was manufactured with white tipping, to be issued to control group smokers post switch, to maintain blinding.



## Subject information pre-study included:

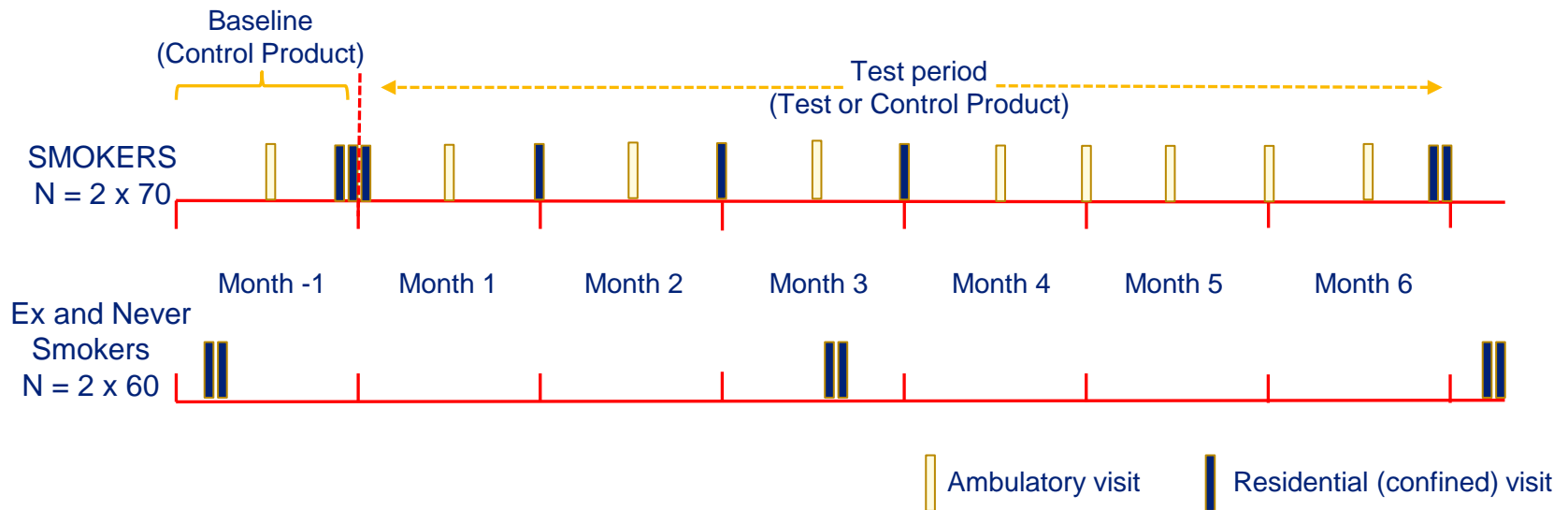


“Laboratory analyses using smoking machines have shown that the smoke of RTP cigarettes contains lower levels of toxicants than commercially available cigarettes of equal ISO tar yield...”

And:

“...to find out whether the body is exposed to a lower concentration of certain toxicants in smoke by the RTP cigarette as compared with conventional cigarettes and whether the reduced load leads to the body responding differently to the toxicants”

# Study Design



140 smokers supplied with control product for 2 weeks; baseline biomarker measures in clinic; 70 switched to RTP, 70 to visually different control (from cork to white tipping)

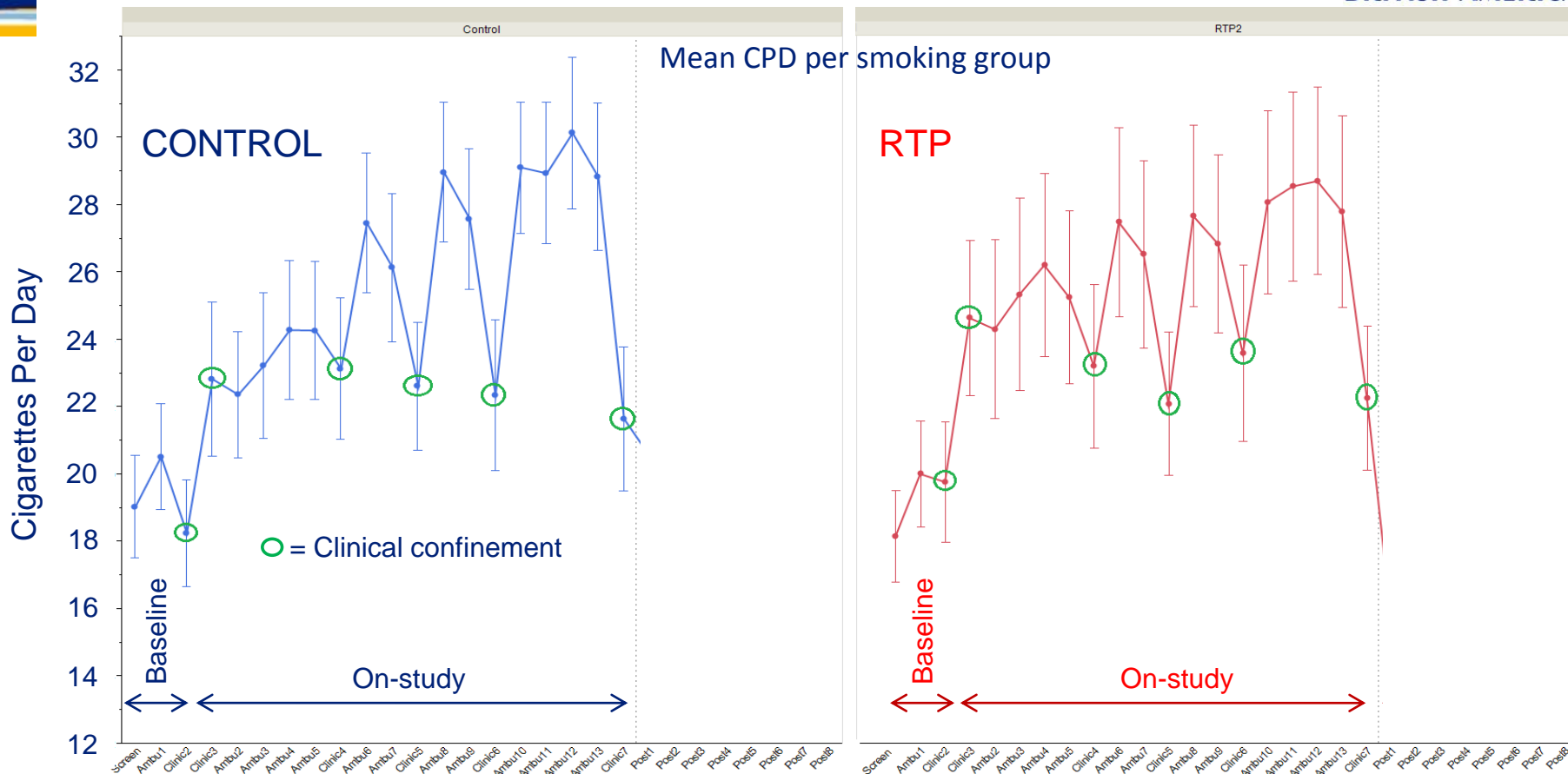
Clinical visits for sample collection/biomarker analysis at 1, 2, 3 and 6 months. Ambulatory visits to collect further supplies of cigarettes

Ex and never smokers provide background levels of biomarkers of exposure and biological effect

# Consumption data (baseline & on-study)



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Each error bar is constructed using a 95% confidence interval of the mean.

## Observed consumption change initiated:

- Increased consumption monitoring (electronic diaries) and added questionnaire
- Set-up of independent Data Safety Monitoring Board (DSMB)
- Addition of post-study monitoring of cigarette consumption

# Reasons for smoking more cigarettes

Scored (4-point scale) pre-set questions



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# Behavioural questionnaire responses

Reasons for changing cigarette consumption (% of subjects responding):



Free text, main drivers for changing consumption:

**Control cigarette:** Availability (free cigarettes) (49%) and smoking faster/'lighter'/shorter/less tobacco\* (40%)

**RTP:** Format (shorter/slimmer) (76%) and reduced sensory (39%)

Presented and scored questions, main drivers for increased consumption:

**Control Cigarette:** free cigarettes, cigarettes not lasting as long as usual brand and 'being on the study'

**RTP:** Cigarettes not lasting as long and considering study cigarettes may be less harmful than usual brand

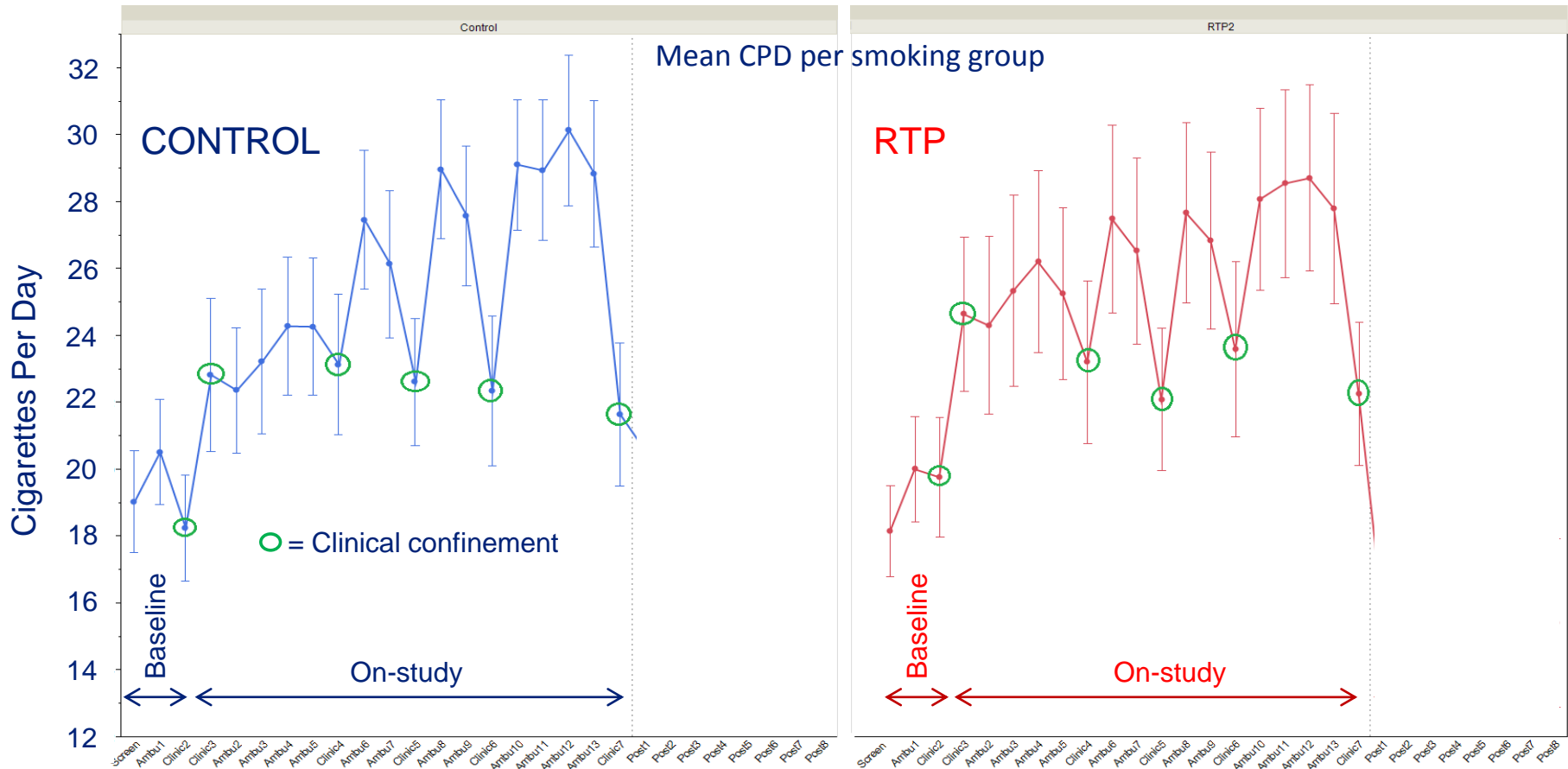
\*NB both controls (pre/post-switch) were identical except for a change in tipping paper colour (cork vs white)



# Consumption data (baseline, on-study & POST-STUDY)



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# Conclusions

- This study was not designed to test the effect of communication on toxicants on smoking behaviour
- However, it seems clear that study design, subject information and product features may influence behaviour and hence study outcomes
- Factors affecting increased consumption may have included communication on reductions in tobacco smoke toxicants, but many other factors may also have had an influence
- By not controlling consumption/behaviour the influence of perception can be studied