REDUCTIONS IN BIOMARKERS OF EXPOSURE TO SELECTED HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS FOLLOWING EXCLUSIVE AND PARTIAL SWITCHING FROM COMBUSTIBLE CIGARETTES TO MYBLU™ ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

Paul Morris| CORESTA Abstract #1929 | October 2021

This work was conducted by Imperial Brands PLC on behalf of Fontem US LLC. Imperial Brands PLC is a service provider to Fontem US LLC

INTRODUCTION

- Tobacco harm reduction (THR) involves providing a means by which adult combustible cigarette smokers, who are uninterested or unwilling to quit smoking, can achieve satisfactory nicotine consumption but with exposure to fewer, and substantially reduced levels of, toxicants associated with burning tobacco

- There is increasing evidence (eg Rudd et al., 2020[1]) that the reduced harm potential of electronic nicotine delivery systems (ENDS) is linked to fewer and/or reduced levels of harmful and potentially harmful constituents (HPHCs) present in their aerosols, compared to smoke generated from tobacco cigarette combustion

- We conducted two identical, randomised, open label, two-part studies, which aimed to compare levels of 14 biomarkers of exposure (BoE) to selected HPHCs associated with tobacco smoking in 72 healthy US adult smoker subjects over 14 days
  - This included complete switching to ENDS and also a dual use (combustible cigarette and ENDS) arm

 1 - Kathryn Rudd, Matthew Stevenson, Roman Wieczorek, Jutta Pani, Edgar Trelles-Sticken, Ole Dethloff, Lukasz Czekala, Liam Simms, Francesca Buchanan, Grant O'Connell, and Tanvir Walele. Applied In Vitro Toxicology. Mar 2020.11-41.

STUDY OBJECTIVES

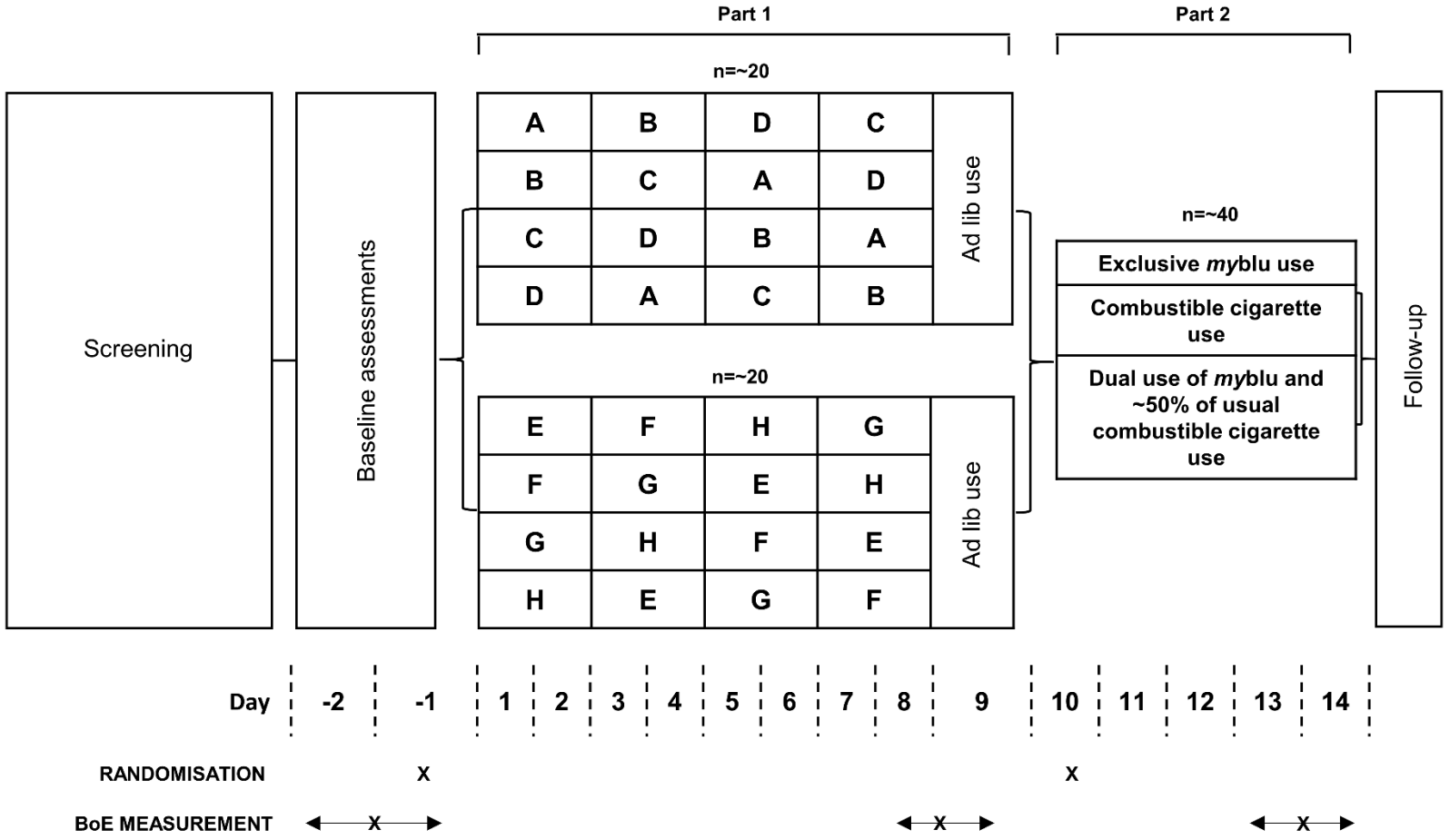
- Part 1: to assess changes from baseline (Day -1, cigarette smoking) levels of 14 tobacco-smoking related BoE following a 9-day exclusive use period of *my*blu™ ENDS products

- Part 2: to assess (in randomised groups):
  - if any **changes in BoE levels (compared to baseline) following exclusive *my*blu use** for 9 days were maintained up to 14 days
  - the **effects on BoE levels (against baseline) following participants' switching back to cigarette smoking** between study Days 9 and 14
  - the **effects of dual use** of cigarettes and *my*blu ENDS on BoE (against baseline) following participants' switching to this between days 9 and 14

BoE	*Associated health risk*
COHb	RDT
NNAL	CA
3-HPMA	RT, CT
S-PMA	CA, CT, RDT
CEMA	CA, RT
HEMA	CA, RT, RDT
3-HMPMA	CA
MHBMA	CA, RT, RDT
o-tol	CA
1-AN	CA, RT
2-AN	CA, RT
NNN	CA
1-OHP	n/a
3-OH B[a]P	CA

RDT = reproductive or developmental toxicant
CA = carcinogen
RT = respiratory toxicant
CT = cardiovascular toxicant

STUDY DESIGN

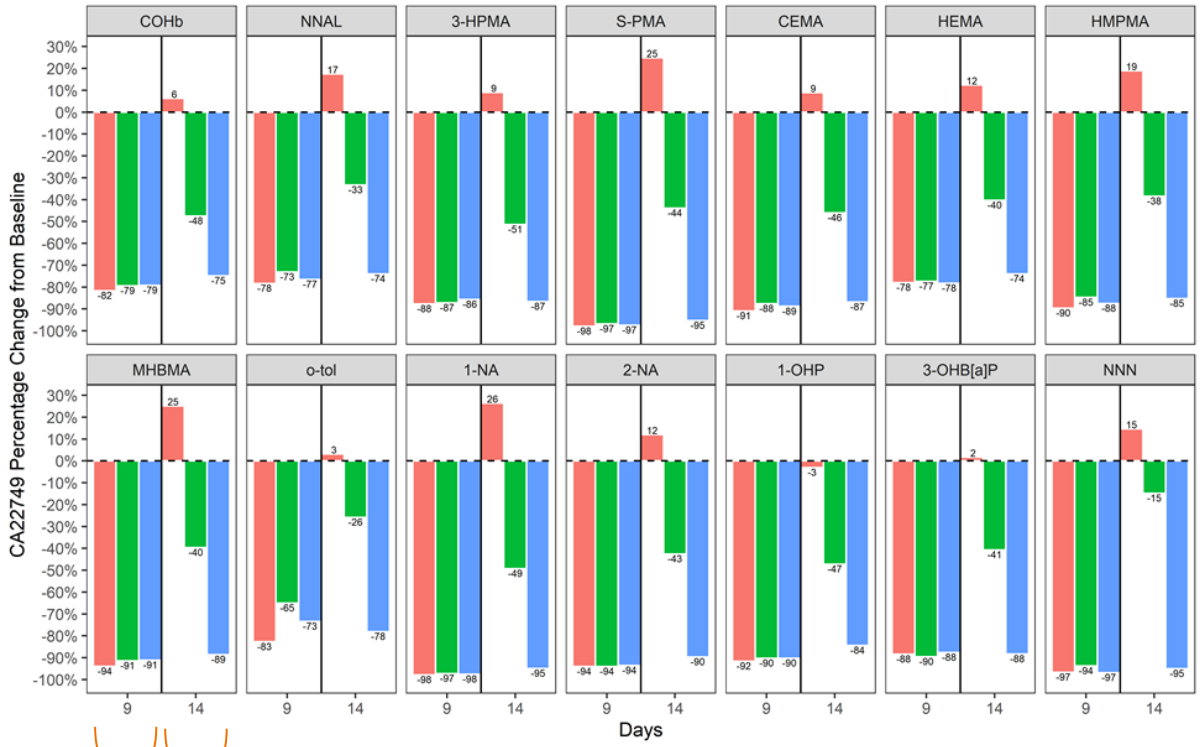


- Total number of participants = 72
- Assessment carried out in two identical clinical studies

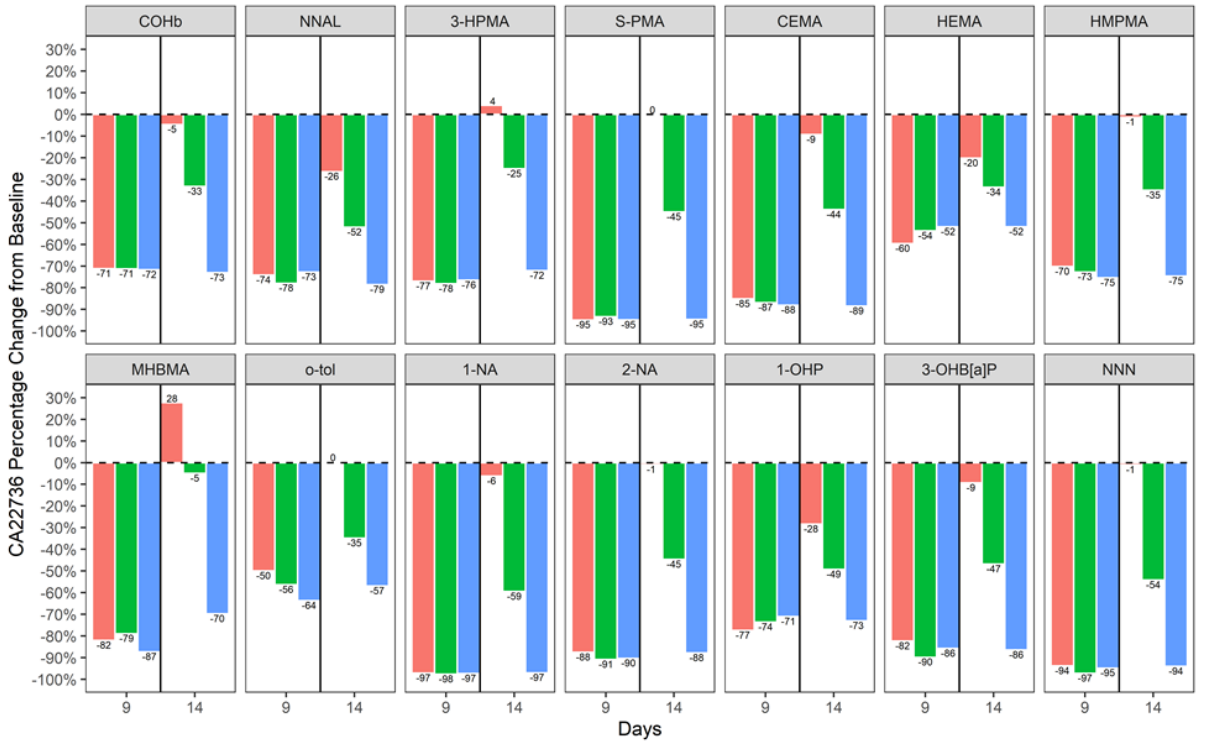
A-H = different *my*blu product variants
n = number of participants

BOE LEVELS TO SELECTED HPHCS WERE SUBSTANTIALLY REDUCED AFTER SWITCHING TO EXCLUSIVE OR PARTIAL MYBLU ENDS USE

Study 1



Study 2



Exclusive *myblu* use period

Period assigned to one of the three product use groups →

switched from exclusive ENDS use to exclusively cigarette smoking cigarette on Day 10

dual-use (50% reported cigarette smoking and ENDS use from Day 10

continued exclusively use of ENDS selected myblu products ad libitum from Day 10

CONCLUSIONS

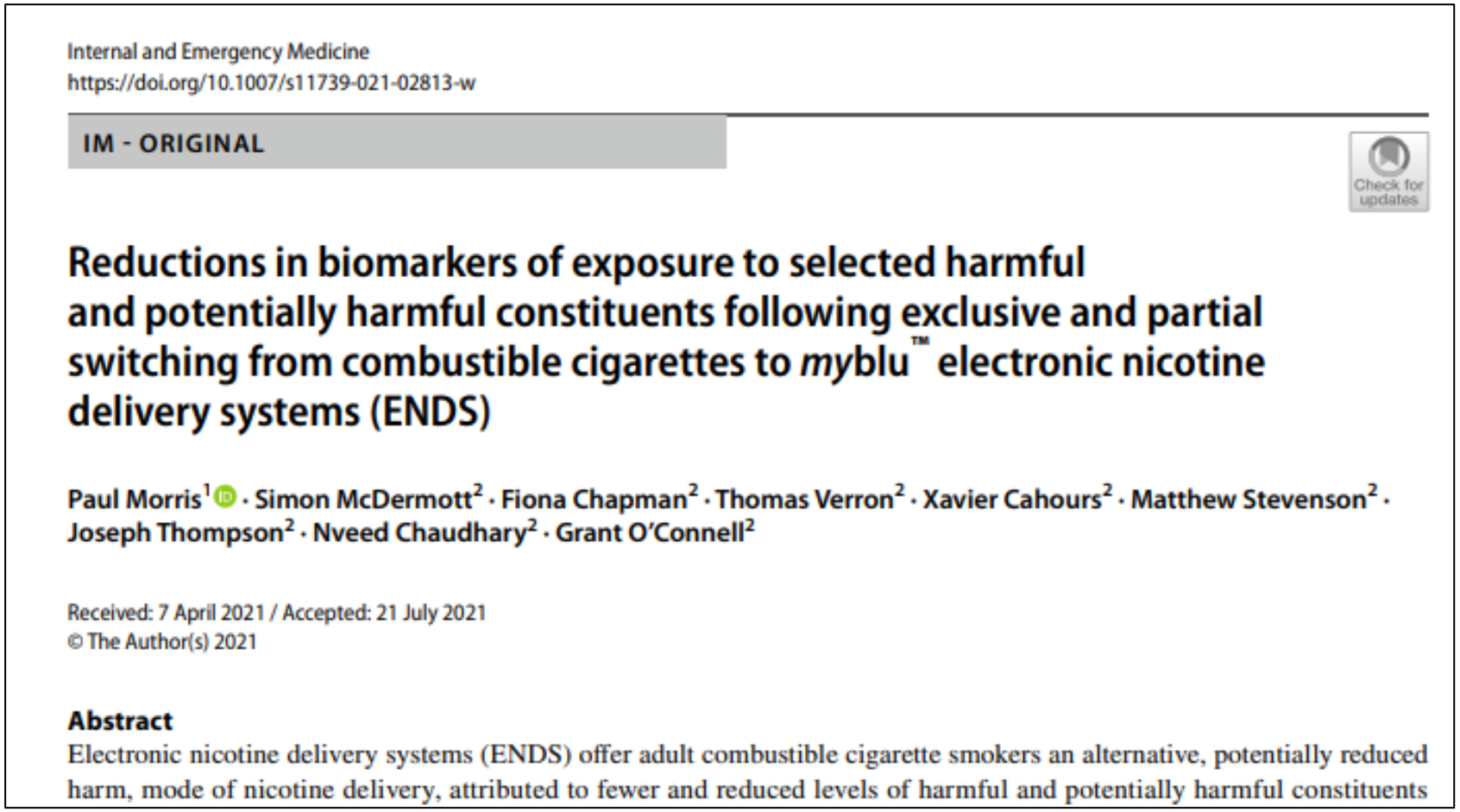
- BoE levels to selected HPHCs - including carcinogens and respiratory & cardiovascular toxicants - were substantially reduced after switching to exclusive *my*blu ENDS use – aggregated average 84% reduction

- Switching back to combustible cigarette use reversed reductions in BoE observed after exclusive *my*blu ENDS use

- Following dual use of combustible cigarettes and *my*blu ENDS (where up to 50% of combustible cigarette usage was replaced with vaping), BoE levels to selected HPHCs were substantially reduced, but not to the same extent as exclusive use – aggregated average 40% reduction

- This data contributes to the weight of evidence that ENDS are an important tool in tobacco harm reduction strategies for adult smokers unwilling to or uninterested in quitting smoking

FOR MORE DETAILS…



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IM - ORIGINAL

Check for updates

Reductions in biomarkers of exposure to selected harmful and potentially harmful constituents following exclusive and partial switching from combustible cigarettes to *my*blu™ electronic nicotine delivery systems (ENDS)

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Abstract
Electronic nicotine delivery systems (ENDS) offer adult combustible cigarette smokers an alternative, potentially reduced harm, mode of nicotine delivery, attributed to fewer and reduced levels of harmful and potentially harmful constituents

Morris P. et al (2021). Reductions in biomarkers of exposure to selected harmful and potentially harmful constituents following exclusive and partial switching from combustible cigarettes to myblu™ electronic nicotine delivery systems (ENDS). Intern Emerg Med. 2021 Aug 26. doi: 10.1007/s11739-021-02813-w.

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