

One year of continuous smoking abstinence: a study on biological and functional changes in healthy adult smokers



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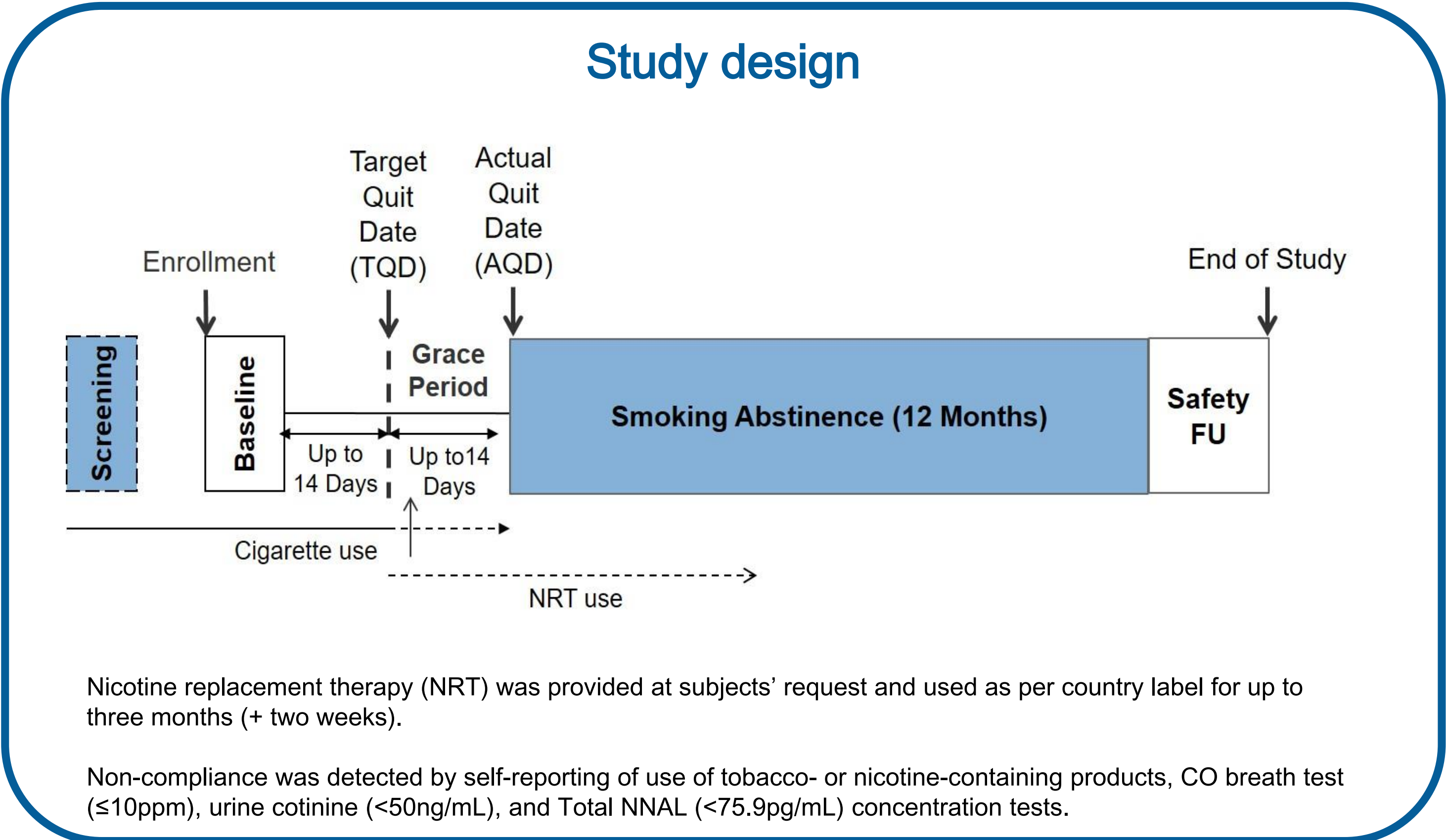
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INTRODUCTION

Long-term exposure to harmful and potentially harmful constituents (HPHC) generated by tobacco combustion is the main cause of harm in smoking.

It is well known that the most effective way to reduce this harm is smoking cessation. However, in most smoking cessation studies, the main focus is on the success rate of the cessation approach/treatment tested, and only limited information is available on functional and biological changes that occur following cessation.

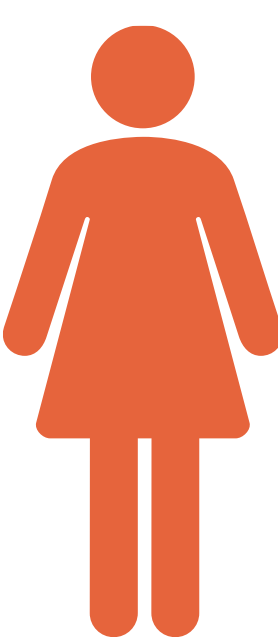
The aim of this study was to assess the reversibility of smoking-related harm following a one-year period of cessation. To do this, we assessed changes in both biomarkers of exposure and biomarkers of effect linked to pathophysiological pathways that underlie the development of smoking-related diseases, such as cardiovascular disease, chronic obstructive pulmonary disease, and cancer.



358
Subjects abstinent for 12 months



Male
50.6%



Female
49.4%

Age: Mean (SD): 43.8 years (9.21)
BMI: Mean (SD): 24.8 kg/m² (3.75)

Demographics

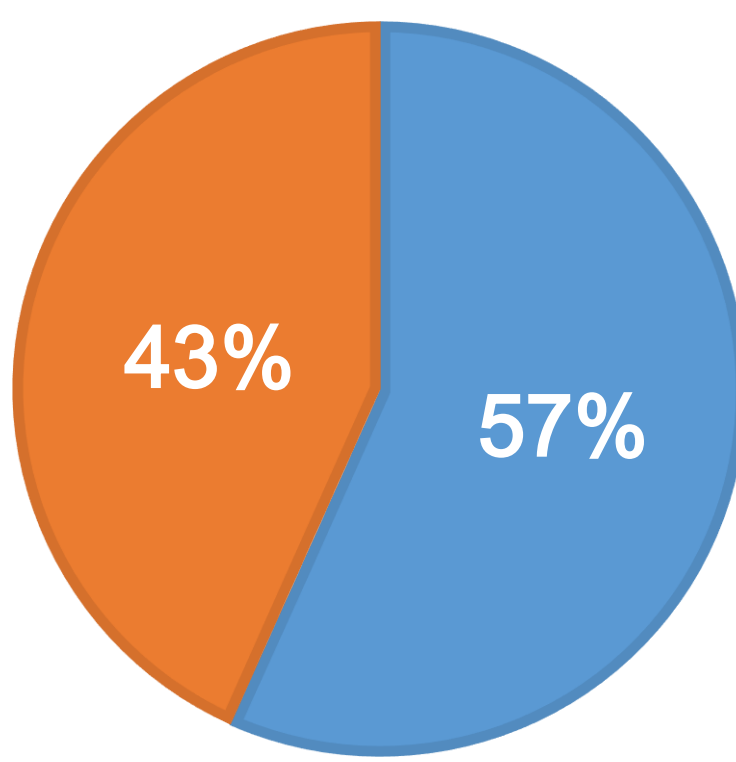


Smoking duration: Mean (SD): 22.8 years (8.76)



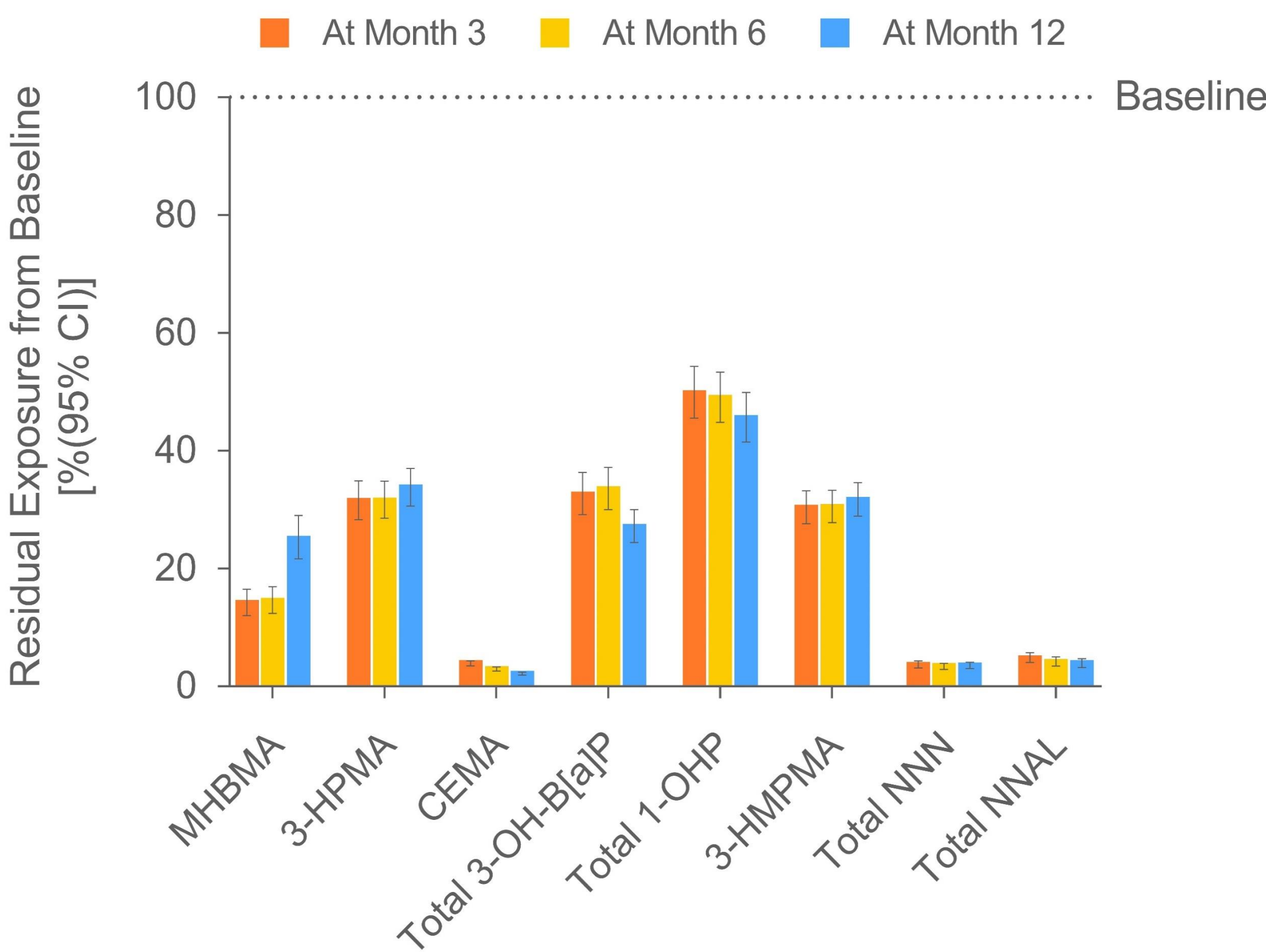
Smoking intensity: Mean (SD): 16.6 cig/day (5.27)

■ Caucasian
■ Not Caucasian

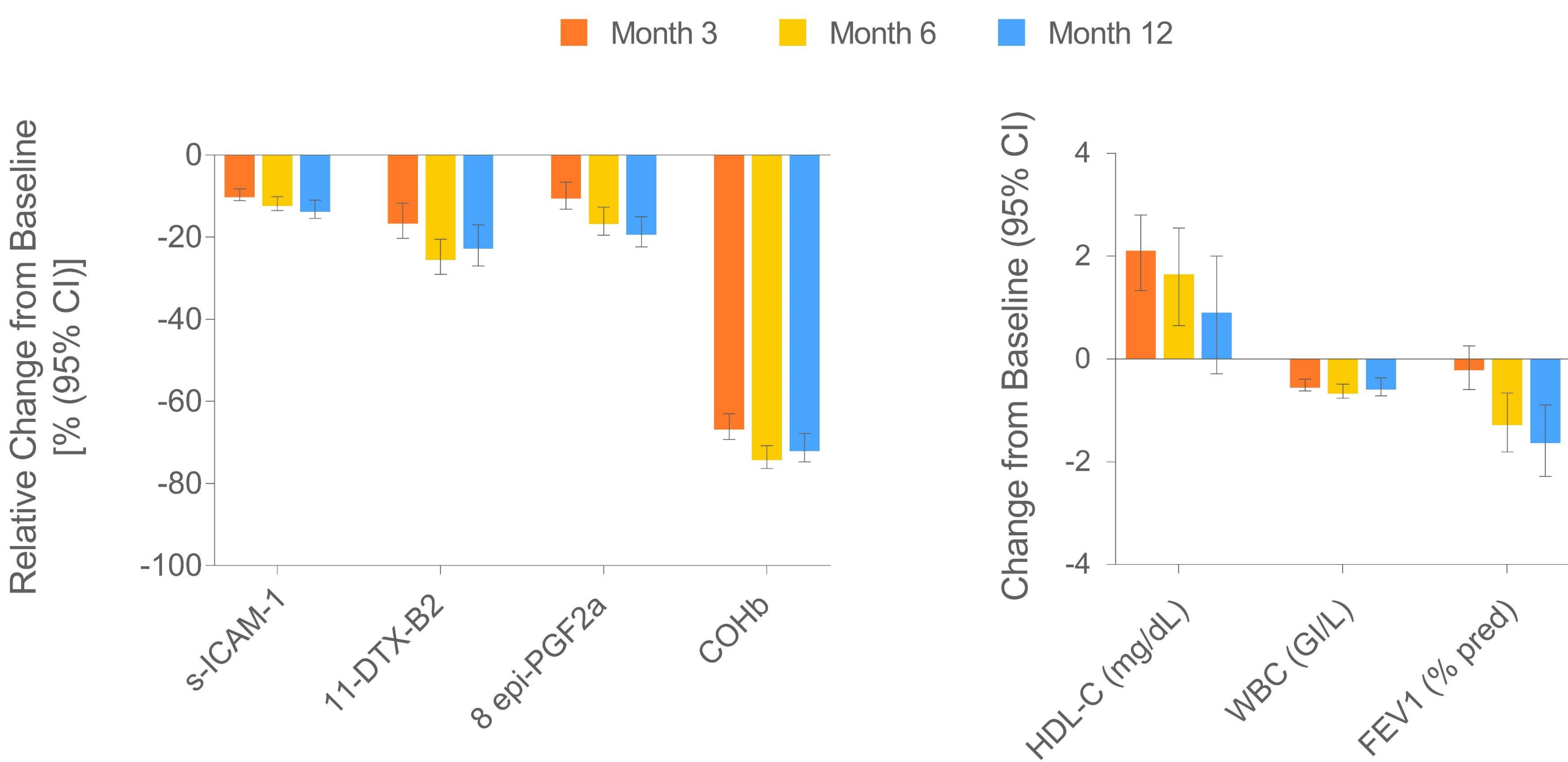


CONTINUOUS ABSTINENCE FROM SMOKING SUBSTANTIALLY REDUCES EXPOSURE TO HPHCS

Levels of Biomarker of exposure to HPHCs were substantially decreased
(range: 54.5–97.9% reduction from baseline)

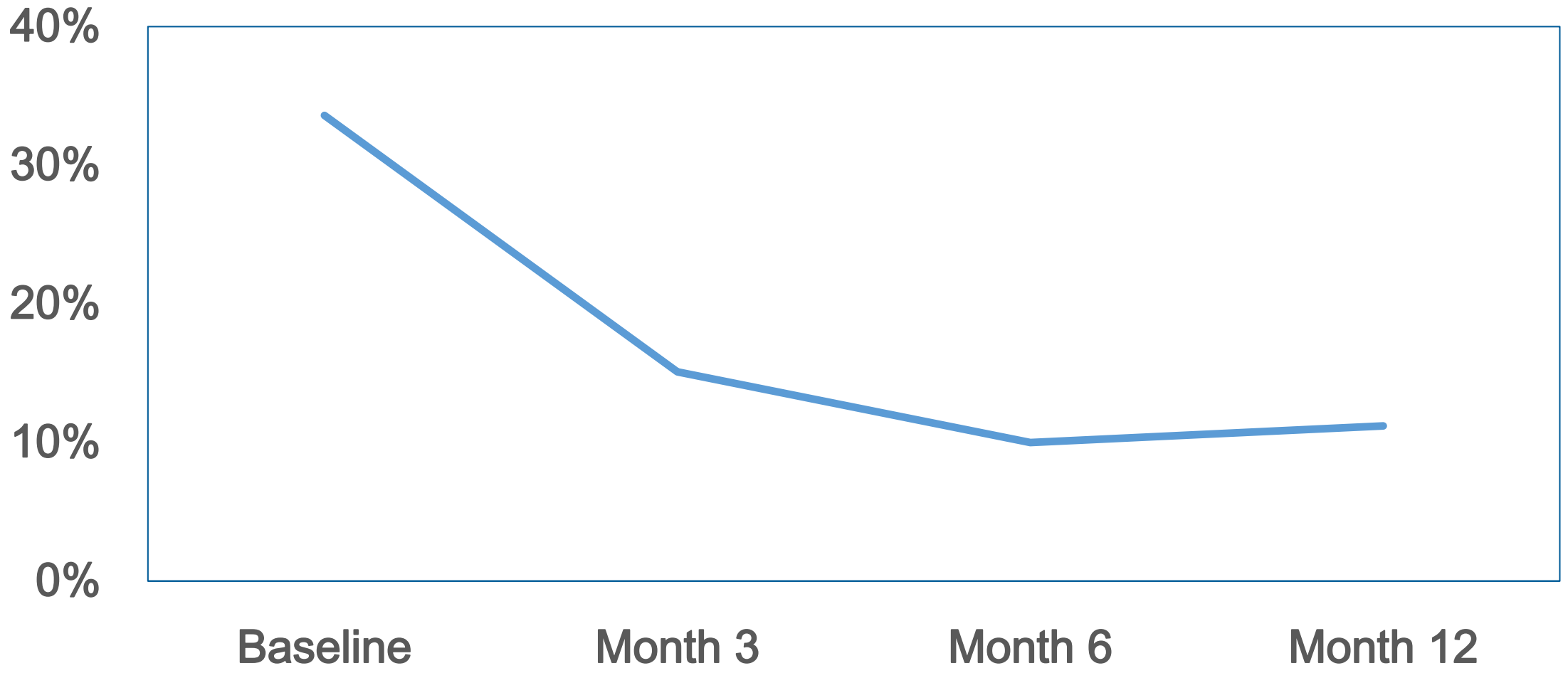


Most biomarkers of effect associated with cardiovascular and respiratory diseases showed favorable changes



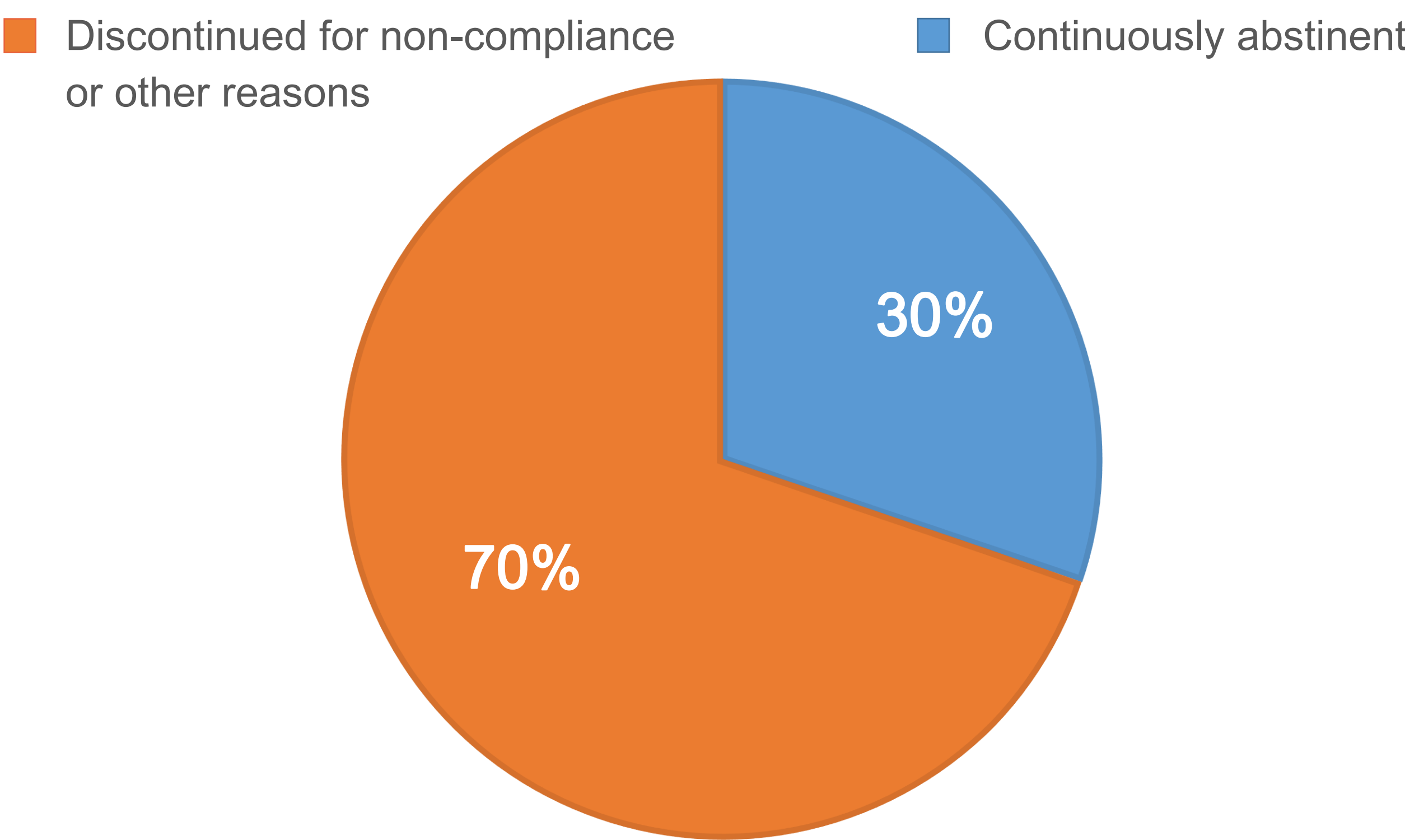
ABSTINENCE LEADS TO FAVORABLE CHANGES IN BIOMARKERS OF EFFECT INVOLVED IN PATHWAYS AND BIOLOGICAL FUNCTIONS THAT CONTRIBUTE TO REDUCED RISK OF DEVELOPING SMOKING-RELATED DISEASES

Subjects who experienced regular need to cough following cessation



Need to cough decreases over time in smokers who quit smoking

Subjects with continued abstinence



SAFETY

Overall, 20 serious adverse effects (SAE) were reported by 17 subjects (1.4%), with one fatal SAE reported. No SAEs were related to study procedures. The majority of adverse effects were mild or moderate in severity.

Overall in the study, there was an increase from Baseline at Month 3, Month 6, and Month 12 in both mean body weight (2.24 kg, 3.46 kg, and 4.06 kg, respectively) and body mass index (0.776 kg/m², 1.18 kg/m², and 1.41 kg/m², respectively).

STUDY CONDUCT

The study was approved by Independent Ethics Committees and Institutional Review Boards in all participating countries, initiated in May 2015, and completed in May 2017.

It was conducted at 42 sites: 14 in the U.S., 13 in Europe, and 15 in Japan.

The study was conducted according to the International Conference on Harmonisation principles of Good Clinical Practice and registered on ClinicalTrials.gov (NCT02432729).