

## **Improved Models to Inform Tobacco Product Regulation**

Cardiovascular Assessment of the Effects of Tobacco and Nicotine Delivery Products

(Project 5)

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### Abstract:

Cigarette smoking continues to be a major cause of cardiovascular disease (CVD). In contrast, the cardiovascular risks of other tobacco products in common use (smokeless tobacco) and new tobacco products (e-cigarettes) are not adequately understood. The FDA will need information about the cardiovascular safety of these products to inform their regulatory decisions. While long-term clinical outcome studies that investigate the cardiovascular risks of tobacco products would be optimal, they take too long to provide the data that the FDA needs now. Disturbances in the function of vascular endothelium (the lining of arteries, which plays an important role in regulating vascular function), in the activation of the autonomic nervous system and increased inflammation, oxidative stress and propensity to thrombosis (clotting) are key mechanisms in the progression of CVD and provide useful and validated biomarkers of CVD risk. These biomarkers form the basis for our model to assess the CVD risks of tobacco product use and secondhand smoke exposure. We will conduct controlled, short-term exposures of human subjects to test products that provide a wide range of nicotine, particle and other cardiovascular toxin concentrations to determine how these components associated with tobacco use adversely affect cardiovascular risk.