Center for the Study of Tobacco Products
Institution: Virginia Commonwealth University
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Project 2: Using user behavior data collected in the clinical lab to test hypotheses about advanced-generation ECIGs and generate population level predictions regarding potential regulatory action
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Project 2 Abstract:
The Center for the Study of Tobacco Products (CSTP) has developed a model for evaluating novel tobacco products using, as exemplars, electronic cigarettes (ECIGs) that heat a liquid that often contains nicotine, forming an aerosol that users inhale. Now, CSTP leverages its methodological and ECIG expertise to pivot from product evaluation to an integrative theme of impact analysis. Specifically, the CSTP proposes methods with which FDA can generate predictions regarding a potential regulation's effects, and then whether or not the predicted effects occur in the population can be tested. The CSTP's model assesses how potential regulation might influence product toxicity (Project 1), user behavior (Project 2), and product addiction/abuse liability (Project 3). In this context, Project 2 will generate new data regarding the effects of advanced-generation ECIGs on user behavior and will contribute, along with Projects 1 and 3, to population-level predictions: Project 4 will test those population-level predictions.
FDA regulations are intended to promote health, but also may have harmful unintended consequences. For example, limiting liquid nicotine to <20 mg/ml, as in the European Union (EU), could drive use of high power ECIGs that deliver more nicotine and other toxicants. Unintended consequences may also occur from other actions, like constraining ECIG nicotine flux (amount of emitted nicotine/unit time), or reducing flavor availability. The consequences of these and other potential regulatory actions may be predicted using results from clinical lab studies in which variables relevant to regulation are manipulated systematically and subjective effects, puff topography (e.g., puff duration, volume), liquid consumption, and nicotine delivery are measured. Results can inform testable population-level predictions regarding device/liquid preferences, amount of liquid consumed, dual ECIG/tobacco cigarette use, and dependence. Thus, Project 2 specific aims are to use established clinical lab methods to examine, in independent studies each involving 68 exclusive ECIG users and 68 non-ECIG using smokers, the extent to which subjective effects, puff topography, liquid consumption, and nicotine delivery are influenced by three potential regulatory actions: (1) limits on nicotine, (2) constraints on nicotine flux, and (3) reduction in flavor availability. Project 2 is informed by the Contextual Knowledge Core that ensures that independent variables reflect real-world conditions. Results will provide new data regarding the role of nicotine concentration, flux, and flavor availability on ECIG user behavior, while informing population-level predictions. Project 4 examines these predictions at the population level. Thus, this project is part of a center with an integrative theme of impact analysis that draws from the team's clinical lab expertise to provide FDA tools that can be used to guide regulation development so that, by the time a regulation goes into effect, methods predictive of population-level phenomena have tested it, refined it, and generated data that show that its health-promoting effects are maximized and unintended consequences are minimized.