Center for the Study of Tobacco Products
Institution: Virginia Commonwealth University
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Project 1: Using toxicity testing data to test hypotheses about advanced-generation ECIGs and generate population-level predictions regarding potential regulatory action
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Project 1 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 1 will generate new data regarding the toxicants emitted by advanced-generation ECIGs and contribute to hypotheses about population-level regulatory impact (with Projects 2 and 3): Project 4 will test those population-level hypotheses.
FDA regulations are designed to promote health, but may also have unintended consequences. For example, limiting ECIG liquids to <20 mg/ml nicotine, as in the European Union (EU), can drive use of higher power ECIGs that aerosolize more liquid/puff, leading users to inhale more nicotine and other toxicants. Unintended consequences may also occur from other action, 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 aerosol research methods that allow rigorous control of key parameters, such as device power, liquid constituents, and puff topography (e.g., puff volume/duration). Outcome measures include amount of aerosol produced, mathematically-predicted nicotine delivery, actual nicotine yield, and aerosol toxicant profile. Results can inform testable population-level hypotheses regarding device/liquid preferences and dual ECIG/tobacco cigarette use. Thus, Project 1 specific aims are to use established aerosol research methods to examine how ECIG emissions are influenced by three potential regulatory actions: (1) limits on nicotine, (2) constraints on nicotine flux, and (3) reduction in flavor availability. Project 1 is informed by the Contextual Knowledge Core that will refine Aim 2 device/liquid choices and provide Aim 3 DIY methods. Project 1 provides new data regarding the role of nicotine concentration, flux, and liquid availability on ECIG toxicity, while informing predictions regarding the consequences of potential regulatory action. Project 4 examines these predictions at the population level. Thus, Project 1 is part of an integrative theme of impact analysis and draws on the team's aerosol research 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.