

CLINICAL AND BEHAVIORAL SCIENCE FOR TOBACCO PRODUCTS

Clear Science for Regulatory Package Submission

The regulatory environment for tobacco and nicotine products is changing. Are you ready to meet the evolving requirements for regulatory package submission?

Battelle provides comprehensive support for clinical and behavioral studies to meet the current and future requirements for your FDA regulatory submission, including a Premarket Tobacco Application (PMTA). We can help you with a broad range of clinical and behavioral studies:

- Clinical Pharmacology Studies
- Use Behavior Studies
- Human Exposure Studies
- Addiction and Abuse Liability Studies

THE BATTELLE ADVANTAGE

Battelle has the people, facilities and experience you need for successful PMTA submission.

- **Experience:** We bring more than 50 years of experience with tobacco and nicotine products, spanning combustible products, smokeless tobacco, oral nicotine products and an extensive array of Electronic Nicotine Delivery Systems (ENDS). We've worked extensively with FDA and with companies applying for premarket approval. Our teams know how to comply with Good Clinical Practice (GCP) guidelines and understand how to design and execute studies that give you the answers you need to maximize your chances of a smooth regulatory submission.
- **Expertise:** Our team includes nationally and internationally known experts who have completed original research and published in peer-reviewed journals. We bring together experts in pharmacokinetics/pharmacodynamics (PK/PD), toxicology, addiction, public health, human factors and related fields under one roof so we can put together the right team for your needs.
- **Efficiency:** We don't just perform contracted studies. We can help you develop a strategy and design your study plan to minimize time and costs and ensure that you have gathered the right data to answer your questions and meet FDA submission requirements. We can even design studies that enable you to gather multiple data sets from the same subjects, keeping costs down and condensing study timelines.



Tobacco and Nicotine Product Experience

- ENDS (e-cigarettes, vapes)
- Oral nicotine products (lozenges, etc.)
- Smokeless tobacco products
- Water pipe/hookah
- Combustible products (cigarettes, cigars, etc.)

- **Support:** Our experienced principal investigators and project managers can guide you through the submission process, so you can be confident that you have the right data and know-how to prepare your submission packet to maximize your chance of success. We can also help you respond to FDA questions on your previous submissions.

OUR FACILITIES

We conduct our clinical and behavioral research in state-of-the-art laboratories in Baltimore, MD and Columbus, OH. Our facilities feature:

- Unique, specially ventilated, experimental chambers designed to safely test combustible and non-combustible aerosol, vapor or smoke-generating products and rigorously assess environmental exposure
- Experimental rooms to conduct data collection for both clinical research studies and clinical trials
- DEA Schedule I licensure to conduct dual-use studies with tobacco and marijuana administration

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OUR SERVICES

We provide end-to-end services, from study design to recruiting, execution and data analysis.

Clinical Pharmacology Studies	<ul style="list-style-type: none"> • Blood, urine, saliva, breath • PK/PD
Use Behavior Studies	<ul style="list-style-type: none"> • Use behavior and consumption • Human use topography
Human Exposure Studies	<ul style="list-style-type: none"> • Biomarkers of harm/exposure (HPHCs, TSNAs, PAHs, metals, etc.) • Second- and third-hand (surface deposition) exposure
Addiction & Abuse Liability Studies	<ul style="list-style-type: none"> • Dependence, craving, withdrawal, initiation, cessation, switching, poly-use • Questionnaire of Smoking Urges (QSU), Minnesota Tobacco Withdrawal Scale (MTWS)

END-TO-END SOLUTIONS FOR THE TOBACCO INDUSTRY

Battelle offers a comprehensive suite of services for tobacco companies. We design and execute studies that give you the answers you need to make business decisions, improve the safety and quality of your products and maximize your chance of a smooth regulatory submission.

Product and Device Development

- Verify product formulations for quality assurance
- Test for shelf stability and reactions with device components (e.g., leachables/extractables)
- Identify HPHCs in product formulations and byproducts produced during combustion or heating

Chemistry

- Conduct validated, regulatory-compliant chemical analysis for accurate characterization of all types of tobacco and nicotine products
- Provide novel chemical analysis and method development to meet unique analytical needs and improve testing sensitivity, precision or speed

Nonclinical and Clinical Studies

- Identify, detect and quantify biomarkers of concern in blood, urine, saliva, breath and tissue for nonclinical and clinical studies
- Conduct analyses to support exposure studies (inhalation toxicology, second-hand/third-hand exposure)

Social Science

- Connect behavioral factors with biomarker analyses to build a more complete picture of product PK/PD

Post-Market Surveillance

- Conduct failure/root cause analysis for investigations of adverse events
- Provide support for product reformulation to address problems with product safety, stability or performance



Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org.

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