

# YOUR CLINICAL PARTNER IN TOBACCO RESEARCH



## TOBACCO

### INPUT: IT'S HOW YOU TURN REGULATORY APPLICATIONS INTO APPROVALS

With over 20 years of experience in execution of comprehensive Phase I-IIa studies, Frontage Clinical Services has full capabilities to conduct a broad range of study types (e.g. PK, confinement and ambulatory) in support of tobacco related studies. With extensive expertise in a wide variety of delivery systems, we are well-positioned to conduct tobacco-focused clinical research studies.

**WE PROVIDE  
SCIENTIFIC DATA  
TO SUPPORT YOUR  
REGULATORY  
FILINGS**

Our modern 36,000 sq. ft. clinical facility is located in Secaucus, NJ. Our purpose-built clinic is comprised of multiple units with 160 beds and is equipped with specialized smoking and vaping rooms. We have a secure limited-access dedicated storage facility for investigational products, with video monitoring and restricted key card entry. Our staff includes 2 full time physicians serving as PIs, and a laboratory manager, project manager and

technical advisor with tobacco clinical research experience.

Our Bioanalytical team has strong scientific expertise in the development of challenging assays for small molecules, biologics and biomarkers using various analytical platforms. We have an outstanding quality and compliance history with more than 30 inspections by the FDA, WHO and Health Canada, and we are CLIA certified. We have a wide range of technology platforms and high capacity with over 65 LC-MS/MS.

### CLINICAL SERVICES:

Our clinical facilities house two separate specialized smoking rooms that include:

- Well-controlled air handling units utilizing displacement ventilation
  - Convective air flows from the floor to the ceiling
  - Separate dispensing rooms and processing laboratories
  - Accommodations for up to 40 subjects at one time
  - Furniture containing non-absorbent fabric for easy cleaning



### STRONG RECRUITMENT OPPORTUNITIES FOR SMOKING STUDIES

- Our Phase I facility is in an ethnically diverse region in northern New Jersey:
  - Less than 7 miles from NYC
  - Access to over 29.5 million healthy volunteers, including over 3 million adult smokers
  - Proximity to extensive mass transit and major airports
  - Located near some of the leading medical facilities in the country

### SUBJECT DATABASE

We have a working database of current tobacco users, ex-users and never-users (defined as <100 product uses in a lifetime). The main tobacco product use categories include machine-made cigarettes, roll-your-own (RYO) cigarettes, cigars, pipe, snuff, oral and electronic nicotine delivery systems (ENDS) devices.

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## BIOANALYTICAL SERVICES

Our state-of-the-art equipment and experienced personnel will quickly and efficiently provide you with the data to support your programs. We provide the resources of a highly skilled, client-focused staff with bioanalysis experience.

## COMPREHENSIVE SUITE PLATFORMS

ICP-MS for trace elements as biomarkers
GC-MS for small molecule biomarkers
LC-MS/MS for small molecule, peptide, oligo, and protein biomarkers
ELISA Assay (single analyte)
Meso Scale Discovery (single or multiplex)
Quanterix Simoa™ HD-1 (single or multiplex)
AppliedBiosystems Real-time PCR Platform (QuantStudio 7)

Tobacco Specific Assays: We are developing a variety of assays tailored to meet your needs in matrices such as human serum, plasma, and urine.

- Biomarkers of Exposure
  - Nicotine, Cotinine and *Trans*-3'-hydroxycotinine
  - NNN and NNAL
  - CEMA, 3-HPMA, 3-HMPMA
  - AAMA and GAMA
  - 1-aminonaphthalene, 2-aminonaphthalene and 4-aminobiphenyl
  - NAT and NAB
- Biomarkers of Biological Effect (Biomarkers of Potential Harm)
  - Oxidative stress (8-epi-prostaglandin F2 alpha)
  - Inflammation (11-dehydro thromboxane B2, plasma soluble intercellular adhesion molecule-I and serum MCP-1)

## BIOMETRICS SERVICES:

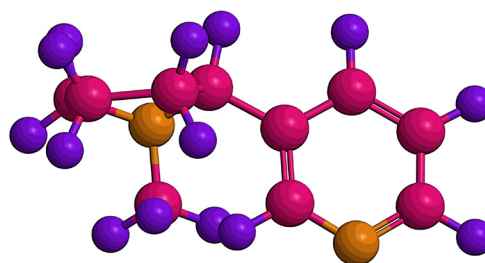
Accurate, statistically sound data delivery is essential for any clinical trial. Rely on a team that can ensure concise and ready-to-file clinical data. Our processes, infrastructure and training are built on industry-leading standards. Frontage's biometrics team will put their expertise and years of experience to work for you.

- Biostatistics (protocol /CSR development support, SAP, interim analysis)
- Statistical Programming (SDTM, ADaM, TFLs), annotated CRF, Define.xml, Reviewer Guides, e-submission package preparation
- PK/PD Analysis and Pharmacometrics

## QUALITY AND SAFETY:

Frontage understands the significance of developing alternative tobacco products for the global population and contributing to this important overall public health concern. We recognize that quality is fundamental to each step in the process of product development. It is an inherent aspect of our services and is the leading criteria in selection of the right outsourcing partner.

As a result, quality management is part of our culture and is embedded throughout the entire organization. We are committed to ensuring that our processes and data generated meet the expectations of our clients and the requirements of regulatory agencies.



3-(1-methyl-2-pyrrolidinyl)pyridine

C<sub>10</sub>H<sub>14</sub>N<sub>2</sub>

Nicotine

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, scientifically-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Rigorous scientific expertise, high quality standards and regulatory compliance is committed to every program. Frontage has enabled many innovator, generic and consumer health companies of all sizes to advance hundreds of molecules through development and file regulatory submissions in global markets allowing for successful development of important therapies and products for patients worldwide.

FOR MORE INFORMATION, CONTACT US AT: [sales@frontagelab.com](mailto:sales@frontagelab.com) OR VISIT US AT: [frontagelab.com](http://frontagelab.com)

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