



Tobacco Clinical Trials

Our facilities are ideally suited for studies on smoking behavior, such as abuse liability and biomarkers of exposure. Our 22 procedure rooms allow for controlled evaluation of tobacco and nicotine products. Our experience with both the pharmaceutical and tobacco industries, coupled with our innovative facilities and expert staff, demonstrate our unique qualifications to conduct these specialized clinical trials.

Product Evaluations

- Tobacco heating products (THP)
- Electronic Nicotine Delivery Systems (ENDS)
- Novel nicotine/tobacco delivery systems
- Traditional oral products

Controlled indoor testing areas with independent ventilation systems, creating negative pressure and venting outside for the evaluation of:

- Nicotine replacement therapies
- Tobacco risk assessment
- Nicotine delivery
- Abuse potential
- Topography

Clinical Operations

- Database of over 60,000 smokers
- Clinics in the U.S.A. and Canada
- Pharmacists with extensive knowledge and experience in preparing and dosing complex clinical trials
- Robust pharmacies include USP 797 clean rooms
- HEPA-filtered extemporaneous compounding room with PowderSafe balance enclosure

Protocol Design and Development

Altasciences is well positioned to advise sponsors on design, conduct, interpretation, and regulatory communication on smoking research.

- **PMTA/MRTP** applications
- **NDA/BLA** submissions

Nicotine Users:

- Cigarette smokers (menthol and non-menthol)
- ENDS – eVapor and eCigarette (open and closed tank systems)
- Moist snuff tobacco (pouch, long-cut, fine-cut)
- Nicotine gum and patch
- Multi-product users

Bioanalysis

- More than 100 dedicated bioanalytical Scientists working with the latest equipment
- Extensive expertise with validated assays for nicotine (including metabolites) in plasma and urine, as well as biomarkers of tobacco exposure

Biomarkers

ANALYTE	
Total NNN	CEMA**
Total NNAL**	Total 1-OHP**
3-HPMA/2-HPMA	Nicotine eqs*
MHBMA**	Nicotine (plasma)
S-PMA**	Cotinine (plasma)
HMPMA	Trans-3'-Hydroxy-cotinine (plasma)

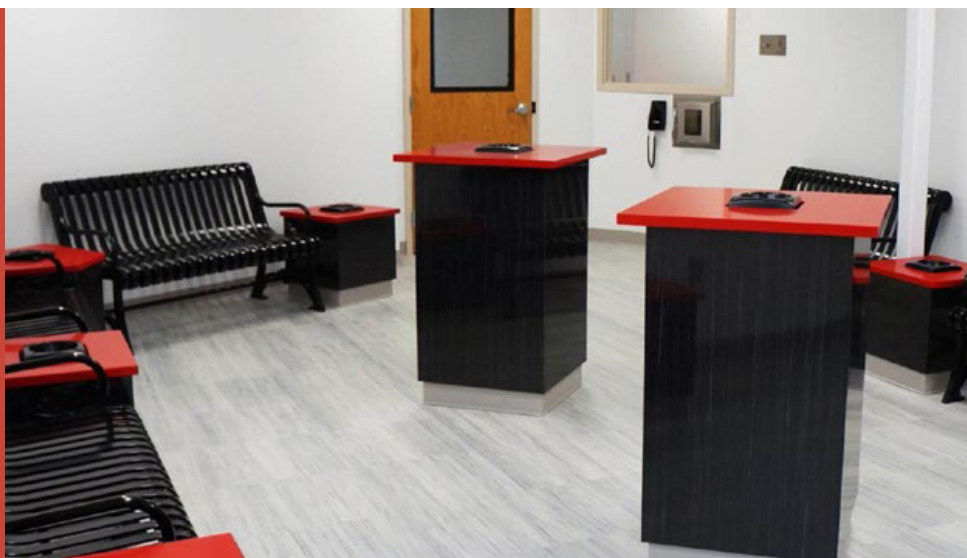
*Nicotine, Cotinine, Trans-3'-Hydroxycontinine, Nicotine-N-glucuronide, Cotinine-N-glucuronide, Trans-3'-HydroxycontinineO-glucuronide

**Development/validation expected to be complete before end of 2019

Clinical Facilities

We have state-of-the-art, purpose-built facilities for all types of smoking studies.

- Fully customizable smoking rooms
- Controlled HEPA filter and air exchange ventilation
- Individual or group smoking rooms allow for one-on-one recording of smoking behavior



Final Analysis

Our Research Services team works closely with the Clinical team to ensure data collection flows seamlessly into the reporting phase. Data from the safety database, assessments and the clinical labs are compiled into a CDISC-compliant submission package.

Bioanalysis

- Method feasibility, transfer, development, and validation in multiple matrices
- LC-MS/MS

Data Management

- Team with over 20 years of experience
- Complete data management plan
- Electronic Data Capture
- CDISC-certified

Biostatistics

- Programmed using SAS®
- Statistical results and appendices for CSR
- Creation of CDISC-compliant, submission-ready package for regulatory approval

Medical Writing

- Expert and meaningful interpretation of pharmacodynamic results