

Tobacco Harm Reduction Solutions



+1 913-333-3000
DrVinceCRO.com
THR@drvince.com

Tobacco Harm Reduction Study Experience

DVCR offers end-to-end clinical and regulatory support from study design through CSR submission. We operate a 100-bed clinical unit that is backed by a team with deep industry experience with both tobacco and nicotine products.



PMTA-Relevant Clinical Evidence

- Abuse Liability
- PK/PD
- Biomarkers of Exposure
- Biomarkers of Potential Harm
- Product use Topography
- Bioequivalence
- Oral Health Endpoints
- Disease Related Endpoints
- Longitudinal Safety Studies



Tobacco Harm Reduction Experts



TC Deluca

Director, THR Operations

TC has over 25 years of clinical research experience. Before DVCR, she led clinical operations at a major tobacco company, gaining expertise in harm reduction and study design.



Neil Sherwood, PhD

Manager, THR Research

Neil holds a Ph.D. in Psychopharmacology and a degree in Experimental Psychology. Since 2016, he has consulted on scientific and regulatory issues.



Collin Gerringer

Manager, THR Operations

Collin, has as over 12 years of clinical research experience in rare diseases, human abuse potential studies, and tobacco and nicotine harm reduction.



Ajesh Raju

Senior Project Manager

Ajesh has 15 + years of experience in the biopharmaceutical and medical device industry, specializing in hands-on project management of tobacco harm reduction studies, including operations, planning, vendor coordination, and daily execution.



Luxurious Phase I Unit

Designed Differently

We operate one of the world's most innovative and technologically advanced research centers, purpose-built to support speed, efficiency and high-quality data. Our facilities provide an ideal environment for seamless study execution.



80,000 square-foot
research campus



100-bed clinical
pharmacology unit



cGMP compliant
pharmacy



State-of-the-art
clinical laboratory



Smoking Rooms

Housed within our facility are seven indoor exposure rooms, including two large and five individual rooms. Each room is equipped with advanced air handling and ventilation/filtration to allow us to conduct these unique types of studies at our site.



Enables PK/AL data collection while volunteers use study products



Dedicated ad-libitum and controlled-use environment



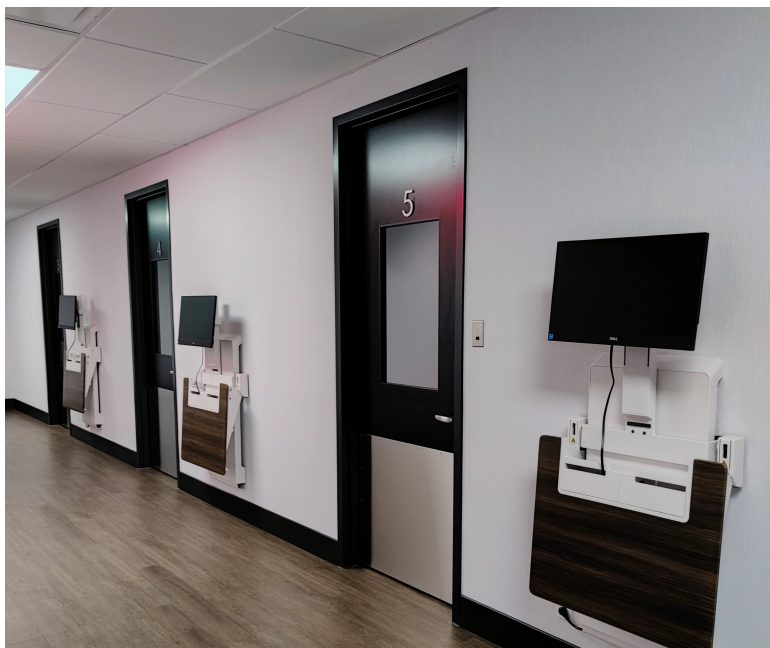
Allows direct observation of product use behavior



Design allows different group sizes



Accommodates different product types



cGMP Compliant Pharmacy

Our pharmacy team has over 50 years of combined experience in early phase clinical research, with expertise in the handling and preparation of investigational products across various routes of administration.

Located within our Phase I unit, the 2,500 square foot cGMP compliant compounding pharmacy contains five distinct areas for the preparation and storage of investigational products:

- Main pharmacy area with closed cell insulation for maintaining environmental controls for ambient storage of investigational products
- Controlled substance licensing for Schedules I-V
- USP 795 compliant negative pressure extemporaneous preparation room
- USP 797 compliant ISO 8 (Class 100,000) anteroom
- USP 797 compliant ISO 7 (Class 10,000) clean room
- Spacious storage area with cold storage units

Pharmacy Features and Equipment

- Thermo Fisher cold storage units with 24/7/365 temperature monitoring
- Secured storage of controlled substances
- Class II, Type A2 biological safety cabinets
- Semi-micro analytical balance for weighing API powder
- Independent narrow spectrum 570nm amber LED lights for handling photosensitive API
- Labconco XPert Filtered Balance System
- HEPA filtration throughout entire pharmacy
- Biometric facial screening
- Biometric facial screening



Expert Insight and Support



At DVCR we have one of the most experienced research teams in the country.

At DVCR, we invest in people, cultivating unmatched expert insight and support. Each member of our diverse research team was hand-selected to provide expertise and practical insights into every facet of study execution.



Robust training



Cutting-edge technology



Positive and uplifting work culture



A workplace designed around collaboration



Unsurpassed Recruitment and Retention

At DVCR, a significant component of being designed differently is how much we value the volunteer experience. This enables us to achieve unmatched speed and diversity in recruitment. You can see this sentiment at work the second you walk through our doors. Additionally, the entire DVCR campus features an array of volunteer amenities, each one thoughtfully planned to enhance the volunteer experience in order to optimize recruitment and retention.



Sports-themed dining room with plush seating and nine large-screen TVs



Gaming room equipped with state-of-the-art systems



VIP lounge with floor-to-ceiling windows and spacious seating



Committed to enhancing the volunteer experience



The DVCR Difference™

Every single detail of our organization is built to deliver excellence. With a highly experienced clinical team, we consistently meet recruitment goals and achieve key milestones for our sponsors.



Flexible Partner

Physician led and adapting to your needs at every stage



Team Continuity

Maintaining key leadership throughout every study



Technology & Innovation

A leader in technology-powered clinical research



Rapid Response Time

Delivering rapid communication and exceptional customer service





Support Services

for Clinical Studies

Full-Service CRO Solutions



**100-Bed
Phase I Unit**



**Phase I-III
Multi-Site
Trials**



**Project
Management**



**Data
Management**



**Biostatistics
& Programming**



**PK/PD
Analysis &
Modeling**



**Clinical
Monitoring**



**Medical
Monitoring**



**Medical
Writing**



**Central
Laboratory
Services**



Phase I-III Multi-Site Trials

By combining our full suite of CRO support services and a network of strategic site partners globally, we manage complex multi-site trials in patients and healthy normal volunteers across a diverse range of therapeutic areas and trial designs.

Our Model

We prioritize sites that align with our principles to help our sponsors reach their milestones faster.



Site ID and Selection

Quality sites are imperative for a successful trial.



Prioritizing Site Payments

Sites require expedited payments to avoid study delays. This reinforces our collaborative, true partnership approach.



Site Engagement

We provide sites with essential tools, support and communication.

Central Laboratory Services

- > Customizable Kits
- > Rapid Turnaround
- > Reduced Site Burden
- > Dedicated Team
- > Data Integration
- > Regulatory Confidence

Florence Trial Operations Platform

The Florence Trial Operations Platform accelerates the study startup and enables seamless document distribution, tracking and remote monitoring across our sites. It provides real-time visibility and quality control, eliminating the need for back-and-forth exchanges and integrates directly with Trial Master Files (TMFs) for efficient filing and document updates. Whether sites use a Florence account or paper ISF, this tool keeps DVCR connected and informed—especially during critical phases such as startup and site activation.



Technology Powered Clinical Research



Integration From Start to Finish

Utilizing cloud-based technology and the highest levels of encryption available, we provide secure data with optimal redundancy, reliability and accessibility.

- Clinspark eSource/EDC and Clinic Workflow Automation System
- Florence electronic Investigator Site File/eTMF
- Wireless Temperature Monitoring
- Wifi-Telemetry with Redundant Server Storage
- Touchless Biometric Access Controls
- Medidata CTMS

By using these and other automated systems, we have transformed standard industry practices to become a leader in technology-based clinical research.



Smarter Faster Data®

We define Smarter Faster Data® as accurate, actionable and audit-ready. This accelerates your time in the clinic and speeds up review, quickly producing clean and robust data through seamless tech integration.



Expedited IRB review via our collaboration with WCG IRB



Strategic partnership with Clario to deliver high-quality cardiac safety data



Dedicated vital signs machines at each bed to reduce data variability



Equipment integration with eSource/EDC for automatic data upload



Deployment of bar code scanning for improved data quality and subject verification



Real-time Sponsor access to live data





CONTACT US

ADDRESS

7401 West 91st Street,
Overland Park, KS, USA 66212

PHONE & EMAIL

+1 913-333-3000
THR@drvince.com

WEB & SOCIAL

DrVinceCRO.com
linkedin.com/company/dvcr

