NAMSA has recently added laboratory services to meet your IVD analytical testing needs.

MRO™ APPROACH
NAMSA is a medical research organization applying our regulatory and quality system consulting, testing services, preclinical efficacy studies, clinical research, and sterilization products to support every phase of medical product development. With NAMSA's MRO™ approach to testing and consulting, you maintain project control while gaining a partner who extends your in-house capabilities, provides specialized expertise at exactly the right time, and manages a completely outsourced project efficiently and effectively.

EXPERIENCE
One of NAMSA's specialties is the design and conduct of clinical trials of IVDs. IVD studies are unique and should be treated differently than an implantable device. To accommodate this, we have smaller, focused teams of IVD experts who understand IVD clinical protocols, and routinely customize data collection and management methods along with monitoring plans to meet the unique requirements of these studies.

NAMSA's consulting and clinical staff includes experienced professionals who are knowledgeable in the field of clinical research and the IVD and medical device industry. Many are licensed or have professional certifications (e.g., CCRA) and have worked in healthcare and/or the industry as RNs, medical technologists, laboratory managers and logistics experts, biologists, toxicologists, chemists, microbiologists, statisticians, field clinical engineers, pathologists and other health professions.

In addition, NAMSA's highly skilled and experienced regulatory and quality consultants have a long history of successful submissions and practical, effective quality system development. We've also conducted beneficial gap analyses and audits for many IVD companies.

NAMSA IVD EXPERIENCE AND EXPERTISE

Type of Assays
- Blood Glucose
- Hemoglobin A1c
- Urinalysis Strips
- Fusion Protein (BCR-ABL)
- Troponin
- Stem Cell Enumeration (CD34+, CD45+)
- Drugs of Abuse
- Theophylline
- Phenobarbital
- Dilantin
- Thyroid Hormones
- Bone Alkaline Phosphatase
- Deoxypyridinoline/ pyridinoline
- Luteinizing Hormone (LH)
- hCG
- Streptococcus A
- HIV
- HLA Typing
- Cystic Fibrosis
- UTI
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Therapeutic Expertise
- Oncology
- Anemia
- Reproductive
- Cardiovascular
- Allergy
- Adrenal/Pituitary
- Bone Metabolism
- Autoimmune
- Diabetes
- Therapeutic Drug Monitoring
- Endocrine
- Infectious Disease
- Fetal Well Being

Technology Expertise
- Molecular Diagnostics
- ELISA
- Automated Instrumentation
- Immunoassay
- Immunohistochemistry
- Calibrators
- Controls

Intended Uses
- Diagnostic
- Research Use Only
- Companion Diagnostics
- Point of Care
- Quantitative
- Qualitative
- Semi-Quantitative

NAMSA CERTIFICATIONS, REGISTRATIONS AND ACCREDITATIONS
NAMSA laboratories are registered with and inspected by one or more of the following:
- United States Food and Drug Administration (FDA)
- Department of Agriculture (USDA)
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
- Registered with FDA as a HCT/P establishment (21 CFR 1271)

NAMSA’s laboratories comply with (as applicable):
- 21 CFR Part 820
- 21 CFR Part 58
- 21 CFR Part 210/211
- 21 CFR Part 11

Certifications/Accreditations:
- ISO 9001 (Minnesota and United Kingdom - Clinical & Consulting)
- ISO 13485 (Northwood, Ohio and Irvine, California – Laboratory Services)
- ISO 17025 (Northwood, Ohio, Irvine, California and Lyon, France – Laboratory Services)

ADDITIONAL INFORMATION
- Regulatory, quality systems and assurance, data management, statistics, and clinical expertise all under one roof
- Proven working relationships with IRBs, Central Laboratories and sites for IVD studies
- Understanding of the various global regulations as they apply to IVD clinical trials and regulatory submissions
- Work with pharma and device companies on companion diagnostics
- Frequent contact with FDA’s Office of In Vitro Diagnostics and Radiological Health (OIR)
- Experience with instrument platforms/systems/database interfaces
- Staff includes members with prior laboratory experience (e.g. medical technologists, laboratory management and logistics expertise)
- Expertise with studies using leftover de-identified samples and prospective studies requiring informed consent, as well as studies where well-characterized banked samples are utilized
REGULATORY
- Regulatory strategies
- Pre-Submission meeting preparation and attendance
- U.S. Regulatory submissions (IDE, 510(k), PMA, HUD, HDE, BLA, Device Master File)
- FDA panel preparation and participation
- International Submissions (Ethics Committee, Technical File, Dossier, STED) and Registrations (EU, Canada, Australia, Japan, BRIC and more)
- U.S. Agent
- Clinical Evaluation Reports

LOGISTICAL SUPPORT
- Custom kit assembly including bar coding
- Chain of Custody tracking of shipments nationally and internationally
- Knowledgeable in area of IATA regulations
- Experience managing ground and Next Flight Out (NFO) couriers
- Logistical support for time sensitive testing of samples to central laboratories for therapeutic drug monitoring studies

QUALITY SYSTEMS
- Quality engineering and quality management
- Quality System development and implementation
- Audits and gap analyses
- Document and design control processes
- Supplier qualification and audits
- FDA manufacturing facility inspection prep/participation/lead
- FDA BIMO inspection preparation/participation/lead

DATA MANAGEMENT
Data management - Instrument data can be uploaded directly into the database via CD/jump-drive or electronic upload through our Electronic Data Capture (EDC) solutions, reducing or eliminating the need for monitoring of a transcript to source. We have expertise in XML, HL7, CSV, and ASCII file formats and solutions for high volume upload. NAMSA has developed clinical databases for data management that are tailored to IVD studies (and longitudinal patient data, when required).

STATISTICS
NAMSA has a dozen statisticians based out of its Minneapolis, MN offices, several of whom have experience in modeling IVD studies and performing the associated analysis.

POST-MARKET STUDIES / SURVEILLANCE
The need for post-market data is on the rise in today’s global market. This data is critical to your marketing efforts, payor coverage and reimbursement levels, and often your ongoing ability to stay in the market. We understand these market pressures and the regulatory rigors required to conduct a successful post-market or non-traditional study.
- FDA mandated post-market studies
- Registries and retrospective studies
- Health Economics studies
- Post-market surveillance
- Literature based meta-analysis

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