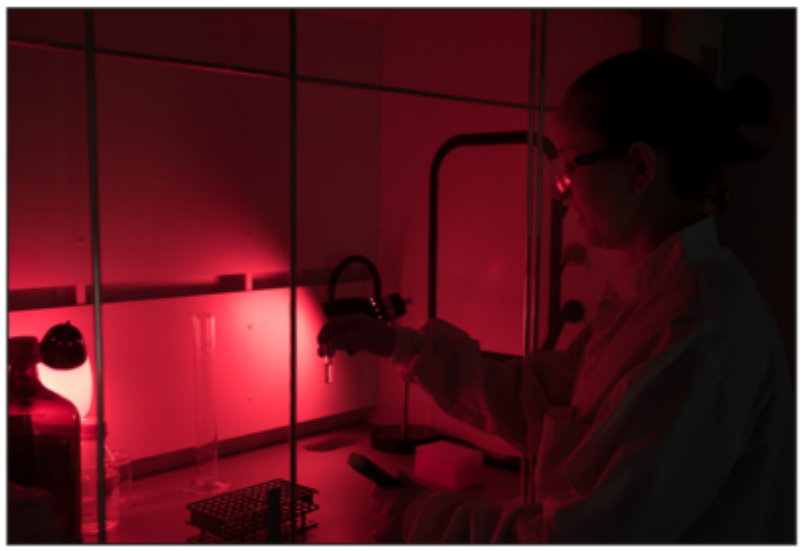


MEDPACE Labs

SCIENCE WITH SERVICE
UNRIVALED QUALITY

Experts

- Medpace Labs are built on a foundation of scientific expertise - ensuring our clients are on the right path in their pursuit of safe and effective products with embedded PhD level scientists.
- Medpace Labs scientists collaborate with therapeutic experts - ensuring difficult studies are designed with the highest quality and efficiency.

Experience

- It's about more than just collecting data. It's about collecting the right data, in the most efficient and effective way, using the right technologies, assays and methods.
- Medpace Labs promotes global coverage with a network of wholly owned labs for large scale studies that require identical sample handling and testing. We collaborate with partner labs to ensure all your testing needs are met.
- >500 protocols, 120,000 randomized patients, 20,000 sites, 60+ countries, serving some of the world's largest and most complex clinical trials.

Execution

- Quality and costs are intertwined. Poor quality will drive up study cost - even with the most well planned project. The cost of rework at the patient and lab level can derail a project.
- Medpace enjoys >99.77% satisfactory or excellent ratings as reported by current Medpace customers on quality of laboratory data.
- Medpace Labs enjoys 85% repeat business reflecting our culture of quality and customer service.

EXPERIENCE THE **POWER** OF **X**®

Depend on Medpace Labs

Medpace provides customized, high quality central laboratory services to the pharmaceutical and biotech clinical development industries. From its origins over 10 years ago as a therapeutically-focused central lab, it has steadily evolved and now offers full-service global central lab support for Phase I-IV. Our clients range from small biotech, to mid-sized pharma, to multinational large pharmaceutical companies. Having worked on some of the most complex and largest clinical trials in the world, we have the expertise and experience to deliver on your clinical projects.

Client Feedback Tells the Story

Your project's success rests on the quality we deliver. To ensure we are meeting our clients' high expectations for quality, Medpace Labs compiles site satisfaction surveys on a regular basis. This site survey consists of 15 attributes relating directly to Medpace Labs project performance. The results include feedback from over 1600 sites on key attributes that are defined as important regarding our overall quality and service levels. Medpace earned an average of 99% positive responses (satisfactory or excellent ratings) across all attributes rated. Focusing in on quality, here are some of the highlights of the surveys.

POSITIVE QUALITY RATINGS

99.8%	99.4%	98.9%	99.0%
Quality of laboratory data	Availability of staff for issue resolution	Data query resolution	Knowledge of personnel

**Satisfactory or excellent ratings*

STRATEGICALLY ALIGNED FOR **GLOBAL STUDIES**

With laboratories in the US, Europe, China and Singapore, Medpace Labs has the global reach and capability to conduct studies, assist with regulatory requirements, and deliver custom solutions specific to your needs, on six continents. Medpace Labs, together with Medpace CRO, has the advantage to deliver services to all Sponsors on a one-to-one basis, or in collaboration with the Medpace team of experts. With full-service central laboratories in Cincinnati, Ohio; Leuven, Belgium; Singapore; and Beijing, China, Medpace Labs state-of-the-art infrastructure, global operating procedures, and medical instrumentation at our four wholly owned labs ensure harmonization of data. Our team of medical and technical experts has extensive experience in all areas of central laboratory services; with >65% of senior management having worked in the industry for >20 years.

Medpace Labs




1992 — Medpace Founded

2005 — Cincinnati, USA; Leuven, Belgium

2009 — Beijing, China

2014 — Singapore

Serving 65 + countries, 20,000 sites, >50M subject visits

Medpace CRO

Medpace Labs is fully integrated with Medpace CRO giving Sponsors the advantage of personalized service in collaboration with the Medpace team of experts across a global footprint.

RELATIONSHIP **EXPERTS**

Relationship management is the key to every stage of the drug development process. Medpace Lab's focus is on communication, collaboration, and commitments, helping us see eye to eye with our sponsors. This focus helps manage expectations from project initiation to regulatory submission. Medpace Labs is adept at putting together strategic teams every step of the way, ensuring that the quality of our wholly owned laboratory testing and clinical operations standards is consistent across the global network of laboratory facilities.

Full Integration for Study Support:

We are dedicated to the highest degree of service. We listen to our clients and develop the scientific, operational and logistical approach that is flexible enough to meet sponsor needs - retaining regulatory integrity and maintaining our high standards for quality and efficiency.

Quality Assurance
- Global analytical integrity and combinable data are maintained utilizing identical methodologies, reagents, calibrators, reference ranges, consistent control programs, and strict compliance to regulatory guidelines

Biorepository Services
- Current storage capacity of >2,000,000 samples
- Secured access and 24/7 temperature monitoring with back-up generator
- Led by a Subject Matter Expert for Clinical Biorepository with >25 years experience
- Procedures follow ISBER Best Practices for Repositories and NCI Best Practice for Biospecimen Resources

Data Management - ClinTrak® Lab
- ClinTrak Lab is a fully integrated decision support system providing real-time information–integration with Medpace ClinTrak
- Real-time global tracking and tracing of specimens
- Real-time data cleaning
- Web-based data portal provides seamless data management delivered "on time" in a single integrated global database

MEDPACE Labs

Logistics
- Customized kits and supplies for all projects
- Microsoft AX system for inventory management
- IATA compliant shipping supplies
- Lab Manuals and Kits–logistics tracking–detailed specific collection and processing instructions
- Relationships with top global couriers–99% on time performance across regions

Project Management
- Served by dedicated project teams who own your project from start to finish on a global basis
- Scientific teams consult regarding assay selection, method development, transfer and validation to appropriate regulatory guidelines

QUALITY DRIVEN
BIOMARKER SUPPORT

Enhanced study outcomes benefit from well planned, scalable and quality driven biomarker strategies at the earliest stages of study design. Medpace provides support from early development through Phase I-IV Clinical Studies.

Biomarkers and the development of Companion Diagnostics play a significant role in study design. A well-defined biomarker strategy should maintain a balance between access to all the traditional platforms and techniques, proteomics, molecular and cellular pathology, and genomics while also offering additional access to “Best in Class” novel biomarker tools supported with therapeutic and scientific understanding. This approach should be medically & therapeutically aligned by impeccable science and quality. The successful execution of a biomarker strategy would require a flexible, fully integrated, modular approach, often integrating several specialist or niche labs with a customer focused project and data management structure to support and serve a truly global patient demographic. Medpace Labs modular and fully integrated approach has benefitted current biopharmaceutical clients.

Flow Cytometry

MEDPACE LABS - A QUALITY DRIVEN & MODULAR APPROACH TO BIOMARKER SUPPORT

Medpace Advantage

Biomarkers - Medpace Value Plus

Biomarkers - Medpace Value - *Science & Therapeutics focus, 20+ years experience, Quality Driven, flexible Global Support*

Quality Driven Excellence

Scientific and Technical Consulting
Validation in GLP/GCP/CLIA environments
Medical, Therapeutic & Regulatory Advice
High- throughput Biomarker Platforms
DNA/RNA Services
Ligand Binding Assays
Flow Cytometry
LC- MS/MS, GC/MS/UPLC
Multiplex Platforms
Fluorescence Microscopy
Global logistics, Project & Data Management

Performed By Medpace

Applied Science/Knowledge

Extension of Assay performance
PK/PD FDA Validations
Bespoke & New Assay development
Large & Small Molecule Expertise
Functional + Receptor Assays
Technology & Method Transfers
IVD development & support
Biobanking & Sample Tracking
Fully Integrated Reporting

Performed by Medpace

Innovation & New Services

Genomics Analysis
& Method Development
Anatomical & Molecular Pathology
IHC testing , FISH & Cytogenetics
Microbiology/Virology
Bioinformatics & Data Mining
Companion Diagnostics Development
Scientific Advisory Boards (Project Driven)
Circulating Tumour Cells & Liquid Biopsies

Extended Services
Integrated Strategic Partners
One Contact with Medpace

Biomarker Support from Early Development through Phase I-IV Clinical Studies

BIOREPOSITORY SERVICES

With the advent of precision medicine, biorepositories are a critical component of any clinical study, given the need for the highest quality specimen management. Key biorepository capabilities must include exacting processes and quality consideration, including handling, storage, and tracking. Scientific expertise is a critical aspect of these project teams.

Medpace Biorepository Services - a key component of Medpace Labs - can deliver biorepository capabilities for your next specimen transfer/archiving project as well as across Phase I-IV. Medpace Labs is an industry leader in terms of customized, high quality service for the pharmaceutical and biotech clinical development industries.

Medpace, a physician-led model combined with highly degreed lab technicians and experts, has the experience and knowledge to handle all biologic specimens for the development of drugs and biologics.

Medpace biorepository services are critical to support clinical development across all study phases.

Medpace offers a distinct biorepository service with a spectrum of capabilities applicable to early and late phase clinical programs. Our clients find that the level of service is much different from a typical commercial storage repository.

Medpace's biorepository service is managed by a field-recognized, subject matter expert (SME) with practical specimen science and clinical experience. We ensure specimen integrity through evidence based processes and can provide efforts to develop client-specific procedures for their unique clinical protocols. These procedures can also be developed in cooperation with the client scientists and downstream application requirements; ultimately available for shared use.

Our biorepository service also provides opportunities to establish prospective studies in cooperation with Medpace's Clinical Pharmacology Unit (CPU). This connection with the biorepository service can enhance the use of specimens and/or annotated clinical data, especially useful to the client for early program decisions or managed in such a way as to track cohorts on a longitudinal basis.

Medpace offers biorepository expertise to provide onsite consultation with the client to determine the most appropriate strategy for managing the control of their specimens within the research or clinical phase environment. Our depth of knowledge allows us to manage bulk specimen moves including the transfer of individual storage units to our facility for management of specimens on a project-basis or as longer term storage.

SPECIMEN LIFE CYCLE MANAGEMENT

Capable of storing all types of specimens, including serum, plasma, urine, DNA, RNA, biopsies and slides, PBMC, and PK, at a variety of controlled temperatures down to –180°C, Medpace Labs offers extensive specimen archiving within a completely secure and continuously monitored environment with multiple, redundant systems backup. With over >12,000 square feet of archive storage space onsite and the capacity to store 2,000,000+ specimens, Medpace Labs specimen archiving is expandable to an almost unlimited capacity within the same facility. Sample archive management is fully-integrated into our Laboratory Information Management System (LIMS), ClinTrak Lab®, allowing for rapid high-volume and cost-effective specimen storage allocation and retrieval.

Medpace Labs offers the flexibility to manage specific sample handling requirements (e.g., relabeling, anonymization, aliquotting), including controlled shipments to referral specialty laboratories, on request.

CUSTOMIZED LOGISTICS SERVICES

Our end-to-end intelligent supply chain management system is tailored to anticipate and respond to your specific needs and provides full lot and expiry date tracking for production and on-time distribution of customized sample collection kits to sites. Medpace Labs has complete control of the preparation, packaging, and delivery of all supplies and materials necessary for sample collection and shipment. Our flexible system ensures rapid preparation and distribution of reliable study and site-specific kits following stringent quality checks.

Medpace Labs provides suitable packaging materials for ambient, refrigerated, frozen, and infectious specimens, and shipping managed through preferred relationships with the best couriers in the industry based upon their documented performance in specific geographic areas.

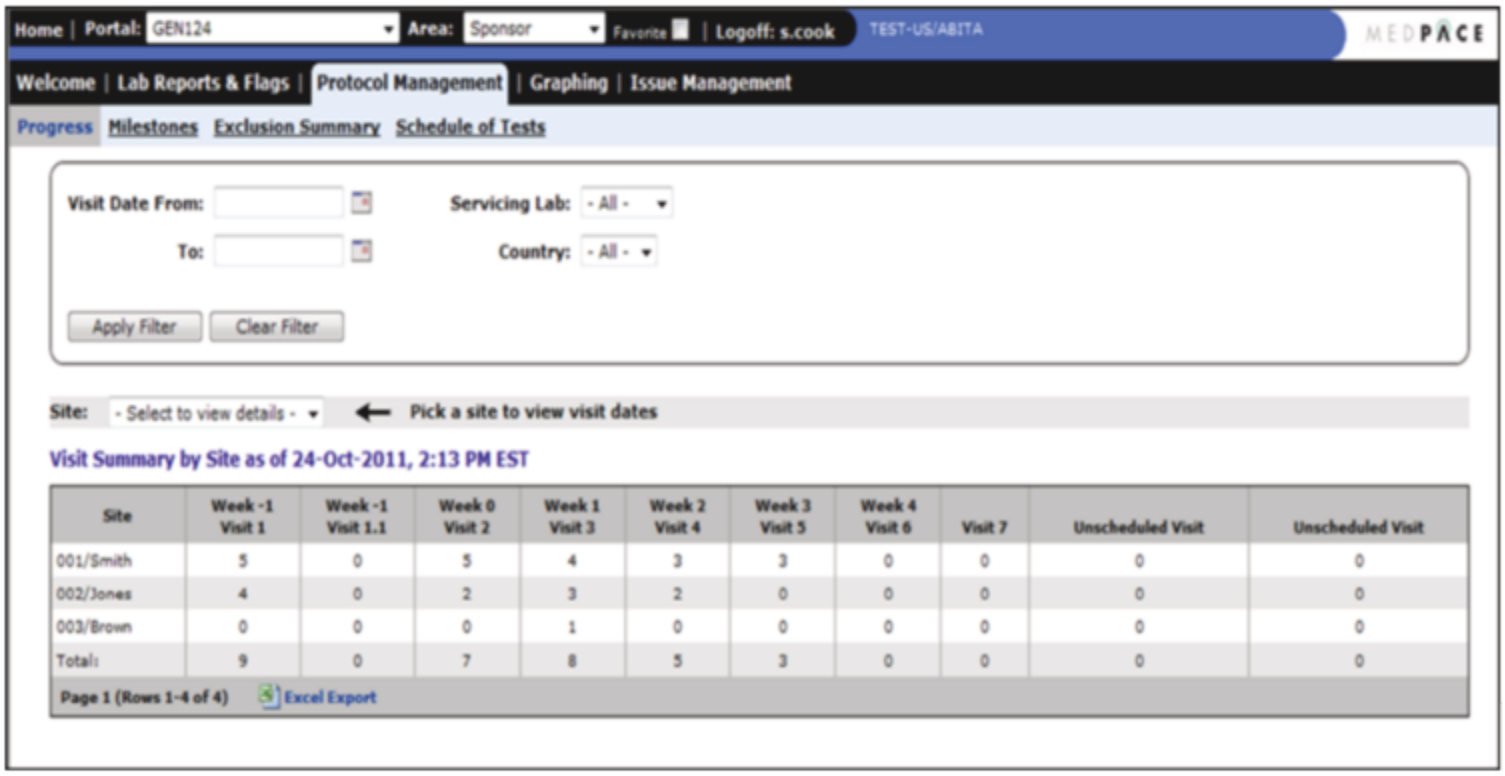
All materials, including selected and prepared packaging and sample collection products, and all shipping procedures are compliant with International Air Transport Association (IATA) regulations.

CLINTRAK® LAB

The point of entry into Medpace Labs, ClinTrak Lab is a full scale Laboratory Information Management System (LIMS) that provides:

- Daily Lab Reports
  - o Allows Sponsors to receive PDFs of the daily lab reports delivered to investigative sites. Includes user-defined flagging and filtering options.
- Study Management Information
  - o Track overall study progress through summary (Subject Counts) or detail (Subject Collection Dates) views of Site and Visit.
  - o Exclusion Summary – View all subjects who screen failed due to laboratory criteria, with exclusion rule and actual result visible by Subject and Visit.
  - o Test Schedule – identify what testing is performed at each visit.
- Query Builder
  - o Dynamic tool provides user-defined filter
- Cumulative Results and Trend Graphing
  - o View results and averages across the course of the study via easy-to-use drill-downs.
  - o View study and site averages or individual patient results for an entire panel of tests.
  - o View trend graphs for selected data.
  - o View results and graphs in either US Conventional or SI units.
- Customized Access
  - o Customized access based on role (Sponsor, Monitor, Site) and location.
  - o Blinding of test results is preserved at all levels (reports, result grids, graphs).
- Study-specific Project Management Pages
  - o Post and view study and regulatory documents.

MEDPACE ClinTrak Labs



Site	Week -1 Visit 1	Week -1 Visit 1.1	Week 0 Visit 2	Week 1 Visit 3	Week 2 Visit 4	Week 3 Visit 5	Week 4 Visit 6	Visit 7	Unscheduled Visit	Unscheduled Visit
001/Smith	5	0	5	4	3	3	0	0	0	0
002/Jones	4	0	2	3	2	0	0	0	0	0
003/Brown	0	0	0	1	0	0	0	0	0	0
Total:	9	0	7	8	5	3	0	0	0	0

BIOANALYTICAL LAB

Leveraging state-of-the-art instrumentation, techniques, and facilities, our team of experts has experience in a broad range of analytical support. Working in a good laboratory practice (GLP) compliant setting, the Medpace Bioanalytical Laboratories provide method transfer, development, validation, and analysis of preclinical and clinical biological samples. We have extensive expertise in developing sensitive methods for LC-MS/MS – qualifying multi-analysis, metabolites, prodrugs, and light- and temperature-sensitive compounds – and we routinely establish and validate analytical methods for mouse, rat, rabbit, dog, monkey, and human species. Our discovery team regularly performs fast PK, bioavailability, and early toxicology studies.

Areas of bioanalytical expertise include:

- Advanced mass spectrometry technologies for bioanalytical analysis
- All bioanalytical aspects for small and large drug molecules according to GLP, OECD, and ICH compliances
- Rapid transition of methods between species and matrices while providing performance according to FDA, OECD, and ICH guidelines

We apply the following bioanalytical services from drug discovery throughout drug development:

- Dose escalating studies, with analysis and reporting capabilities for thousands of samples within short timeframes
- Method development, feasibility, and validation
- Nonclinical toxicokinetic (TK) studies
- Pharmacokinetic (PK) screening
- Clinical PK/bioavailability studies
- Bioequivalency studies
- Bioavailability studies
- Drug discovery
- Drug-drug interaction studies
- Pre-clinical and clinical sample analysis
- Clinical study-compliance samples

Bioanalytical Laboratories provide complete services for labeling, shipping, and storing biological samples. Our facility features:

- Refrigerated storage (4°C)
- Low temperature storage (-20°C, -70°C, and -80°C)
- Emergency back-up electrical and heating services
- Video security
- Onsite archive facility
- Bar coding system

State-of-the-art equipment, bioanalytical capabilities/instrumentation, and software includes:

- AB Sciex 6500 high resolution Q Trap LC-MS/MS systems
- AB Sciex 5600 high resolution LC-MS/MS systems
- API-5500 Sciex Q trap LC-MS / MS Systems (with SelexION-Ion Mobility)
- API-4000 Sciex LC-MS / MS Systems
- UFLC Shimadzu LFLC/HPLC LC-30XR Systems (19,000 PSI)
- HPLC Shimadzu UFLC / LC-20 Systems
- ELISA instruments with Absorbance, Fluorescence, Luminescence
- MSD Sector Imager 2400 (Multiplex)
- Eppendorf qPCR (Realplex)
- GC-MS
- Flow Cytometer and Microscope
- PerkinElmer ICP-MS NexION 300X for Metal compounds
- Validated Watson LIMS System vs7.3
- Automated sample preparation and TomTech Quadra SPE 4
- Fully Validated (IQ/OQ/PQ, Software) Systems
- Complete services for labeling, shipping, and storing biological samples

LOCATIONS

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Bioanalytical Labs

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MEDPACE Labs

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