MICROBIOLOGY LABORATORY SERVICES FOR CLINICAL STUDIES

Infectious disease studies have grown in complexity with traditional microbiology methods increasingly supplemented with new molecular techniques. These important studies provide rapid and accurate data that facilitate improved understanding of disease mechanism and enhance clinical outcomes. The development of successful infectious disease therapeutics requires access to a global patient population, sophisticated testing platforms, and expert microbiologists, to ensure delivery of a consistent and quality-driven solution to these complex studies.

Medpace and IHMA offer our clients specialized microbiology expertise in a fully-integrated global central laboratory environment. Our quality science and integrated technology deliver seamless sample management, tracking, data reporting, and collaborative project services for your trial.

CENTRAL MICROBIOLOGY LAB SERVICES:

- Consultation during study development
- Management of phase I – IV studies
- Infectious disease serology
- TB testing (QuantiFERON-TB Gold)
- Viral load testing
- Bacterial and fungal culture and identification
- Bacterial and fungal molecular characterization
- Antimicrobial susceptibility testing
- Adopt new assays needed to support unique product development strategies

THE MEDPACE - IHMA ADVANTAGE: MAKING THE COMPLEX SEAMLESS™

Our fully-integrated microbiology and central laboratory model streamlines your program and results in more consistent and higher quality outcomes.

Experience & Execution

Access top research scientists with deep expertise in infectious diseases and deliver regulatory-quality results.

Expert Project Management

The PM is the point of contact for study setup, clinical site management, kit resupply orders, reporting, and data transfers.

Efficient & Cost Effective

Centralized coordination of project management, logistics, supplies, site and data management, contracting, and invoicing.

Single Source of Data

IHMA integrates harmoniously with Medpace's full-service clinical trial management and reporting.

30 YEARS OF SPECIALTY MICROBIOLOGY EXPERTISE - QUALITY RESULTS

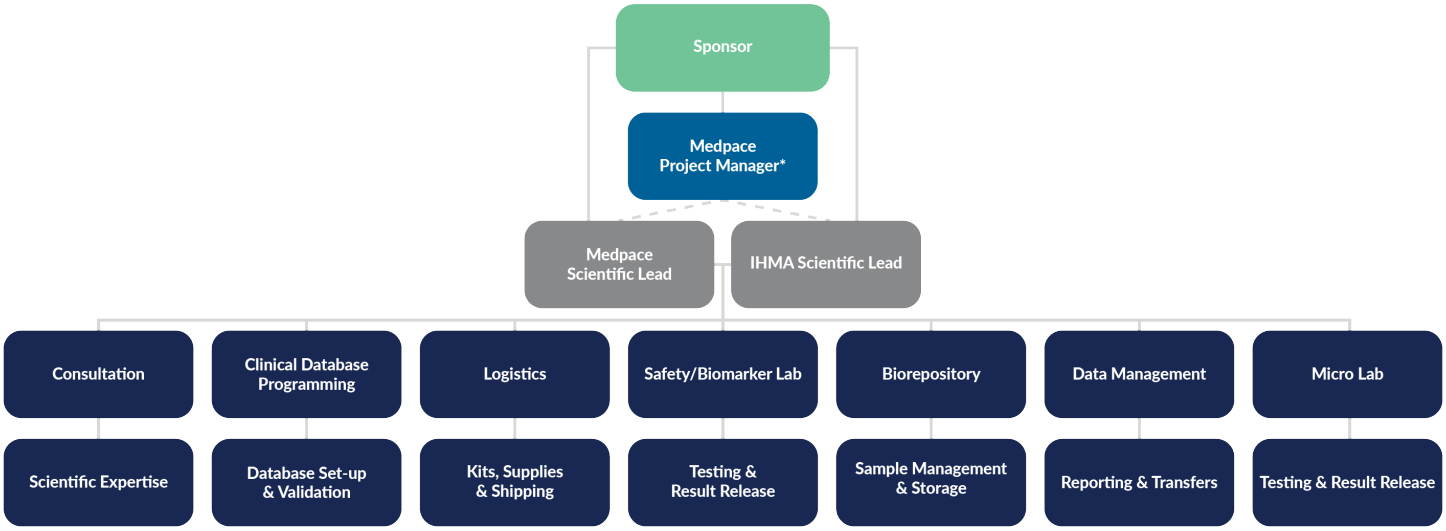
Both IHMA and Medpace were founded in 1992 and are highly-regarded companies in the industry. The Medpace-IHMA strategic partnership (since 2015) combines Medpace's outstanding central laboratory project management and global logistics capabilities with IHMA's world-renowned experts in microbiology and anti-infective discovery and development. Together, we bring you the experts, the experience and the quality execution to support your anti-infective studies.

PROJECT MANAGEMENT - SINGLE POINT OF CONTACT

The Medpace Project Management (PM) team is structured to minimize errors, shorten timelines, and maintain an active and consistent dialogue with your operational teams.

You will work with the same dedicated PM team throughout the entire study (including study start-up, maintenance, and database lock/closeout) which provides stability and consistency.

IHMA's experts work hand-in-hand with Medpace's PM and clinical teams. Integrated processes and our interfaced Lab Information Systems (LIS) make the microbiology laboratory a critical part of the entire central lab study team.



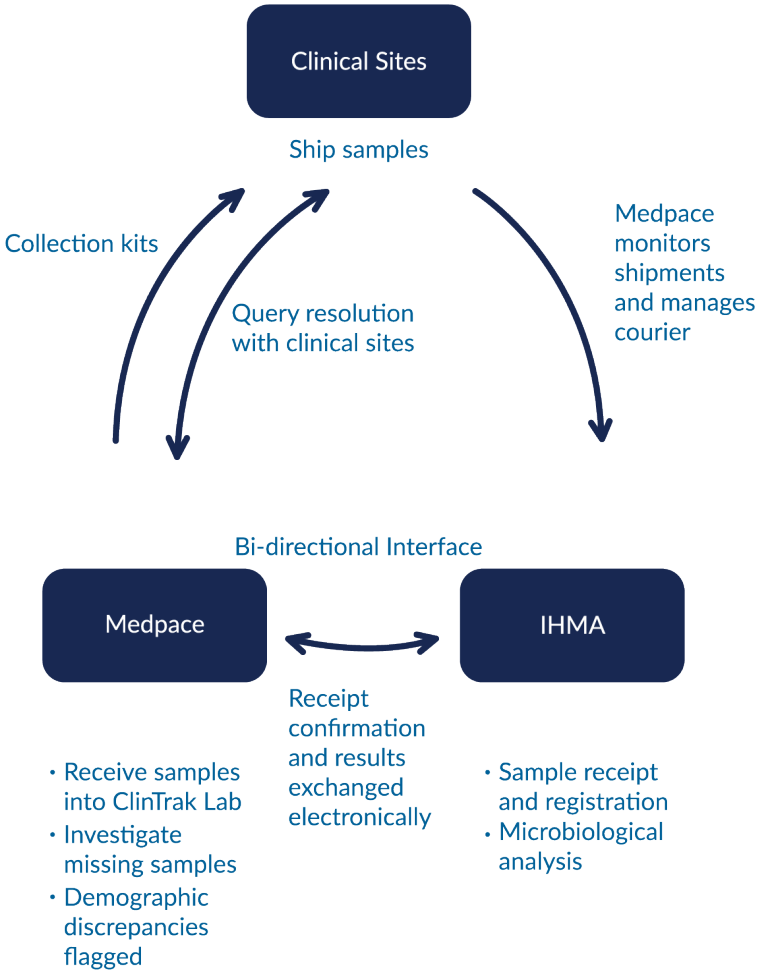
*The PM is the point of contact for study setup, clinical site management, kit resupply orders, reporting, and data transfers.

IHMA's extensive antimicrobial development expertise combined with Medpace's full suite of central laboratory capabilities provides highly robust services to support the development of anti-infective products.

INTEGRATED LOGISTICS AND SAMPLE MANAGEMENT - CUSTOMIZED FOR YOUR PROGRAM

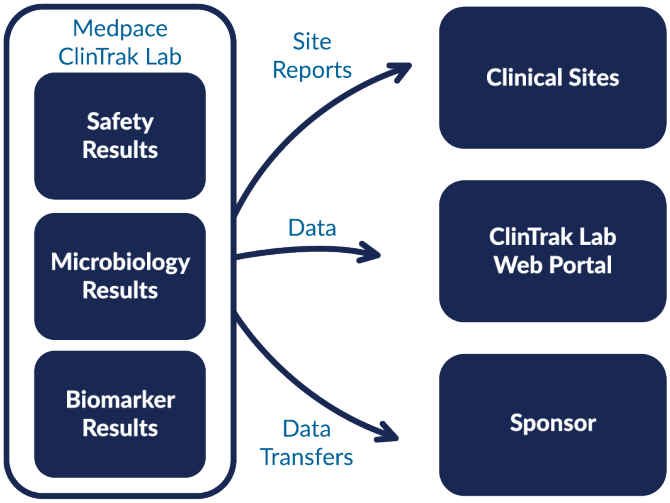
Medpace has extensive experience in managing logistics and tracking samples from the clinical sites to the central laboratory.

Studies that require the central microbiology laboratory to perform the primary cultures on clinical specimens real time are set up so that the site ships directly to the microbiology lab. Whether samples are received at Medpace or at IHMA, the samples are registered in Medpace's ClinTrak® Lab LIS which flags any sample issues or demographic data discrepancies. The Medpace data team engages the clinical sites to obtain clean study and demographic data in real time for both central lab and microbiology samples. This reduces the turnaround time to report out clean data to sites and the study sponsor.



REPORTING - QUICK AND ACCESSIBLE

Sponsors and the clinical sites receive all reporting from one database at Medpace. There is no need for the sites or Sponsor to receive reports from multiple sources, check multiple websites for results, or coordinate data transfers from multiple databases. Medpace is responsible for reporting out all data (e.g. safety, biomarkers, and microbiology) to the clinical sites and the Sponsor.



Clinical Site Report

- Medpace faxes/emails all lab reports with safety, biomarker, and micro data to clinical sites real time, the day that results are released

Web Portal

- All data available on ClinTrak Lab Web Portal for clinical team's review
- Clinical sites can review data specific to their site (safety testing, biomarkers, and microbiology)
- Single login to web portal since all data is in ClinTrak Lab

Database

- Single database of safety, biomarker, and microbiology data
- All data transfers from Medpace - only one set of data transfer specifications for Sponsor to manage (not multiple labs)

ABOUT MEDPACE LABS

Medpace offers pharmaceutical and biotechnology companies comprehensive global central lab services during all stages of the development process. Focused on both the scientific and service aspects with wholly owned laboratories in the US, Europe, China, and Singapore, Medpace has the global reach to conduct studies, assist with regulatory requirements, and deliver custom solutions specific to each Sponsor's study needs on six continents. Preparation, packaging, and delivery of all supplies and materials necessary for specimen collection are managed within the laboratory.

Medpace offers clients the following central laboratory services:

- Scientific consulting
- Project management
- Logistics management
- Comprehensive testing for routine safety, biomarkers, and specialized assays such as PCR, microbiome, and NGS sequencing
- Short and long term sample storage
- Data Management
- ClinTrak Lab web portal for study documents, study progress and result viewing

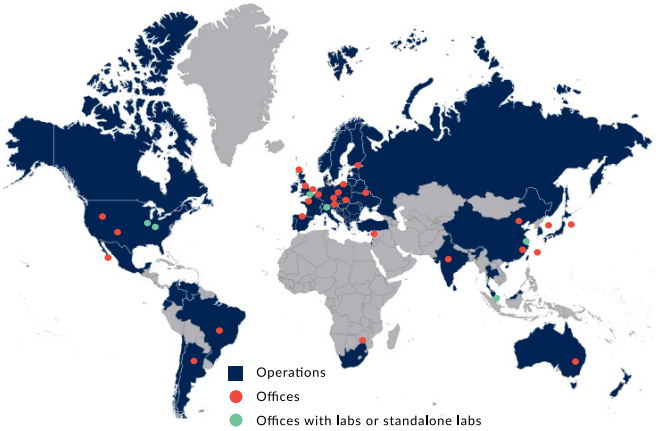
Medpace's goal is to provide the highest quality analytical support to our Sponsors and investigational sites. Medpace is compliant with the Clinical Laboratory Improvement Amendment (CLIA-88) in the US and accredited by one of the industry's leading regulatory organizations, the College of American Pathologists (CAP), at all locations.

ABOUT IHMA

With a CAP accredited, New York State Licensed and CLIA certified microbiology laboratory in the US and CAP accredited microbiology laboratories in Switzerland and China, along with an office in India, IHMA's global presence and extensive anti-infective expertise provides both consultative and laboratory services to support global anti-infective development across all phases; from pre-clinical through clinical trial microbiology testing to post-market AMR surveillance. IHMA's bacterial and fungal expertise spans the full spectrum of clinical and molecular microbiology testing and analysis requirements needed to:

- Support anti-infective small molecule and biologics (e.g. bacteriophage therapeutics), vaccines, and in vitro diagnostic identification and susceptibility testing devices.
- Collect and process clinical specimens.
- Qualitatively and quantitatively culture and identify clinically relevant microorganisms (bacterial and fungal).
- Perform a wide variety of *in vitro* antimicrobial susceptibility tests (disk diffusion, gradient strip, CLSI reference broth microdilution & CLSI reference agar dilution).
- Molecularly characterize and type resistant microorganisms of interest by Whole Genome Sequencing (WGS) and PCR-based assays.
- Adopt new assays needed to support unique product development strategies.
- Support phage-based therapeutics via phage plaquing of patient specimens and bacterial sensitivity testing to phage therapeutics.

MEDPACE AND IHMA - STRATEGICALLY MAPPED TO SUPPORT GLOBAL TRIALS



4 CAP ACCREDITED MEDPACE CENTRAL LABORATORIES

USA CHINA *

BELGIUM SINGAPORE

3 CAP ACCREDITED IHMA MICROBIOLOGY LABORATORIES

USA CHINA *

SWITZERLAND

**The Medpace China central lab includes a microbiology lab jointly operated by Medpace and IHMA*

MAKING THE COMPLEX SEAMLESS™