MYER

Clinical Research Services

Our Mission

Our mission is to help your organization achieve its human health and commercialization goals by offering high impact, high-quality clinical research services with unmatched speed and affordability

MYER

Unique Challenges

Facing Biopharma Companies

- Tight timelines
- Limited budgets
- Lean teams

MYER's Unique Solutions

Tight Timelines: Our goal is to help propel your organization through the value creation threshold, whether it be first in man or Phase I-III studies

Limited Budgets: MYER provides near-shore operations and strategies to reduce costs and deliver a bigger return for your dollar

Lean Teams: MYER brings decades of experience specially tailored to the needs of fast and lean entrepreneurial organizations like yours

Therapeutic Areas

- Cardiology
- Critical Care
- Dermatology
- Endocrinology
- Gastroenterology
- Immunology
- Infectious Disease
- Neurology
- Oncology & Hematology
- Ophthalmology
- Rare Diseases
- Respiratory
- Urology
- Women's Health
- Vaccine Development

Therapeutic

Classes/Modalities

- Biologics
- Small Molecules
- Biosimilars
- New Chemical Entities
- New Indications
- Medical Devices

- Peroral
- Intravenous
- Transdermal
- Inhalation
- Transmucosal
- Devices

Patient Reach

- MYER has access to Mexico's extensive private healthcare network and the government operated IMMS system
- IMMS is the Mexican Social Security Institute
- There are 58 million people covered by IMSS
- It is a tripartite system funded equally by the employee, employers, and the federal government

Resources

- Fully ICH-GCP compliant
- 3 dedicated investigational sites
- Coverage of countries top population and medical centers
- 22 Principle Investigators
- Regulatory Expertise (US and regionally based)
- Statisticians (US and regionally based)
- Experienced CRAs & Clinical Coordinators
- Biotechnologists

Value Proposition

Our aim is to deliver rapid turnaround times, scientifically sound research and market relevant value

Case Examples

Sponsor	Phase	Description
Motif Biosciences /Covance	II/III	Phase III, randomized, double-blind, multicenter study to evaluate the safety and efficacy of intravenous iclaprim versus vancomycin the treatment of acute bacterial skin and skin structure infections suspected or confirmed to be due to Gram-positive pathogens
Boehringer Ingelheim	II/III	Global Registry, on Long-Term Oral Anti-Thrombotic Treatment in Patients with Arterial Fibrillation (Phase II/III)
Takeda / Quintiles	II	Phase III, randomized, double-blind, event-driven, placebo-controlled, multicenter study of the effects of Canagliflozin on renal and cardiovascular outcomes in subjects with type 2 diabetes mellitus (T2DM) and diabetic nephropathy.

Case Examples

Sponsor	Phase	Description
JANSSEN/QUINTILES	III	Phase III, randomized, double-blind, event-driven, placebo-controlled, multicenter study of the effects of Canagliflozin on renal and cardiovascular outcomes in subjects with type 2 diabetes mellitus (T2DM) and diabetic nephropathy.
Grünenthal / ReSolutions	III	A randomized, double-blind, multi-site, comparator-controlled, Phase III trial to evaluate the efficacy and safety of a fixed-dose combination of tramadol hydrochloride and diclofenac sodium in acute moderate to severe pain after third molar extraction.
Takeda/QUINTILES	III	A Phase III, open-label study to determine the long-term safety and efficacy of Vedolizumab subcutaneous in subjects with ulcerative colitis and Crohn's disease.

Case Examples

Sponsor	Phase	Description
JANSSON	III	A phase III, randomized placebo-controlled, double-blind study of apalutamida plus androgen deprivation therapy (ADT) versus ADT in subjects with metastatic hormone-sensitive prostate cancer (mHSPC)
Boehringer Ingelheim	III	A multicenter, randomized, double-blind phase III trial to evaluate the efficacy and safety of BI 695502, plus chemotherapy, versus Avastin, plus chemotherapy, in patients with advanced nonsquamous non-small cell lung cancer.
EISAI/QUINTILES	II	A randomized, Global, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety Of one's daily oral Avatrombopag for the treatment of adults with thrombocytopenia cytopenia associated with liver disease prior to an elective procedure

Case Examples

Sponsor	Phase	Description
Lilly ICOS	II	A randomized double-blind placebo-controlled parallel group phase 2 study with Baricitinibib in patients with systemic lupus erythematosus (SLE)
Starpharma/ quintiles	III	A phase three double-blind, multicenter, randomized placebo-controlled study to determine the efficacy and safety of SPL7013 Gel (VivaGel) to prevent the recurrence a bacterial vaginosis
Chiesi / ICON	II	A 52-week, double-blind, double-dummy, randomized, multinational, multicenter, 2-arm parallel group, an active-controlled clinical trial of a fixed combination of beclomethasone dipropionate plus formoterol fumarate plus glycopyrronium bromide administered via PMDI (CH 5993) versus indacaterol/glycopyrronium (ULTIBRO) via DPI in patients with chronic obstructive pulmonary disease.

Case Examples

Sponsor	Phase	Description
GSK	III	A randomized, double-blind, double-dummy, parallelogram, multicenter study of one Staley Fluticasone Furoate/Vilanterol 100/25 mcg inhalation powder, and twice daily Fluticasone Propionate 250 mcg inhalation powder in the treatment of persistent asthma in adults and adolescents already adequately controlled on twice daily inhaled corticosteroid and long-acting beta-2 agonist.
BMS Icon	II	A multicenter, randomized, double-blind, placebo-controlled, parallel group, phase II study to evaluate the clinical efficacy and safety of BMS 986165 in subjects with moderate to severe psoriasis
Ferrying / PPD	II	a randomized, double-blind, placebo-controlled, multicenter study investigating the efficacy and safety of Mesalamine 4 g extended release granules (sachet) for induction of clinical and endoscopic remission in active, mild to moderate, ulcerative colitis

Case Examples

Sponsor	Phase	Description
Akebia /Quintiles	III	A randomized, open-label, active-controlled study evaluating the efficacy and safety of oral, Vadadustat for the correction of anemia in subjects with non-dialysis dependent chronic kidney disease (NDD-CKD)
Akebia /Quintiles	III	A phase III, randomized, open-label, active control study evaluating the efficacy and safety of oral Vadadastat for correction of anemia in subjects with incident dialysis-dependent chronic kidney disease (DD-CKD) (INNO2VATE-correction)

Case Examples

Sponsor	Phase	Description
Laboratorios Silanes	III	Efficacy and safety of Metformin glycynate vs Metformin hydrochloride for metabolic control and mediators of inflammation in patients with type 2 diabetes
Merz	II	Multicenter, Randomized, Double-blind, Parallel-group, Dose-response Study of Three Doses Xeomin® (incobotulinumtoxinA, NT 201) for the Treatment of Upper Limb Spasticity Alone or Combined Upper and Lower Limb Spasticity in Children and Adolescents (Age 2 - 17 Years) with Cerebral Palsy
Akebia / PDD	III	A randomized, open-label, active-controlled, study evaluating the efficacy and safety of oral Vadadustat for maintenance treatment of anemia in subjects with dialysis-dependent chronic kidney disease (DD-CKD) (INNO2VATE-conversion)

Case Examples

Sponsor	Phase	Description
AB Science	III	Phase II, multicenter, double-blind, parallel group randomized, placebo-controlled, study to evalute the efficacy and safety of masitinib in patients with mild-to-moderate Alzheimer's disease
AB Science	III	A 96 Week, Prospective, Multicentre, Randomized, Double-blind, Placebo-controlled, 2 Parallel-groups, Phase 3 Study to Compare Efficacy and Safety of Masitinib 4.5 mg/kg/Day Versus Placebo in the Treatment of Patients With Primary Progressive or Relapse-free Secondary Progressive Multiple Sclerosis
Covance	III	Multicenter, Randomized, Double-blind, Double-dummy, Active-comparator, Event-driven, Superiority Phase III Study of Secondary Prevention of Stroke and Prevention of Systemic Embolism in Patients With a Recent Embolic Stroke of Undetermined Source (ESUS), Comparing Rivaroxaban 15 mg Once Daily With Aspirin 100 mg

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