

OPHTHALMOLOGY CLINICAL RESEARCH CAPABILITIES

WCCT Global offers an end-to-end solution for conducting Phase I-II ophthalmic clinical trials. WCCT combines site ownership with a network of ophthalmology research centers, investigators, and KOLs to provide its partners the experience and services necessary to accelerate the development of new treatments. Since 2006, WCCT has performed over 40 clinical trials in the area of ophthalmology.



CLINICAL DEVELOPMENT HIGHLIGHTS

WCCT has served as a partner from Phase 1 through Phase 3 trials in the following indications:

- Open-Angle Glaucoma
- Ocular Hypertension
- Dry Eye Disease
- Corneal Disorders
- Myopia
- Presbyopia
- Uveitis

WCCT maintains numerous partnerships with KOLs and key-collaborating research sites across the country. With 10+ sites in southern CA and another 20+ sites throughout the U.S., WCCT brings together a breadth of ophthalmic specialists with access to a variety of patients and combines this with our depth of knowledge in early clinical development.

Additionally, WCCT's Clinical Pharmacology Unit (CPU) is located near Los Angeles, CA, providing access to an ethnically diverse population of ophthalmology patients, particularly for early phase ethnobridging and proof of concept trials. WCCT's 180-bed CPU in Cypress, CA is capable of conducting various ophthalmic procedures and assessments in-house including: BCVA, slit lamp examination, lens opacification, IOP measurement, gonioscopy, specular microscopy, and more.

SAMPLE EXPERIENCE LIST

Phase	Indication	Study Population	Study Design Elements
I	Corneal Injuries	Healthy Volunteer	Bioavailability; Double-Masked; First-in-Human; Multiple Ascending Doses; Pharmacodynamics; Pharmacokinetic; Placebo-controlled; Randomized; Safety and Tolerability
I	Ocular Inflammation	Healthy Volunteer	Double-Masked; Single Dose; Multiple Doses; Pharmacokinetic; Placebo-controlled; Safety and Tolerability;
I	Glaucoma	Bilateral OHT or Chronic Open-Angle Glaucoma	Double-Masked; Pharmacodynamics; Pharmacokinetic; Placebo -controlled; Safety and Tolerability; Single Ascending Dose
II	Acute Anterior Uveitis	Non-infectious Acute Anterior Uveitis	Double-Masked; Randomized; Safety and Efficacy
II	Corneal Epithelial Disorders	Moderate to Severe Corneal Epithelial Disorders	Double-Masked; Parallel Group; Placebo-controlled; Randomized; Safety and Efficacy
II	Presbyopia	Presbyopia	Double-Masked; Parallel Group; Pharmacokinetic; Randomized; Safety and Efficacy
II	Reduction of lower lid steatoblepharon	Moderate-to-severe, bilateral lower eyelid steatoblepharon	Double-Masked; Placebo-controlled; Randomized

OPHTHALMOLOGY CASE STUDY

A Phase 2, Single-Masked, Randomized, Crossover Study Of The 24-Hour Intraocular Pressure (IOP) Lowering And Systemic Exposure Of *** Alone And In Combination With Latanoprost



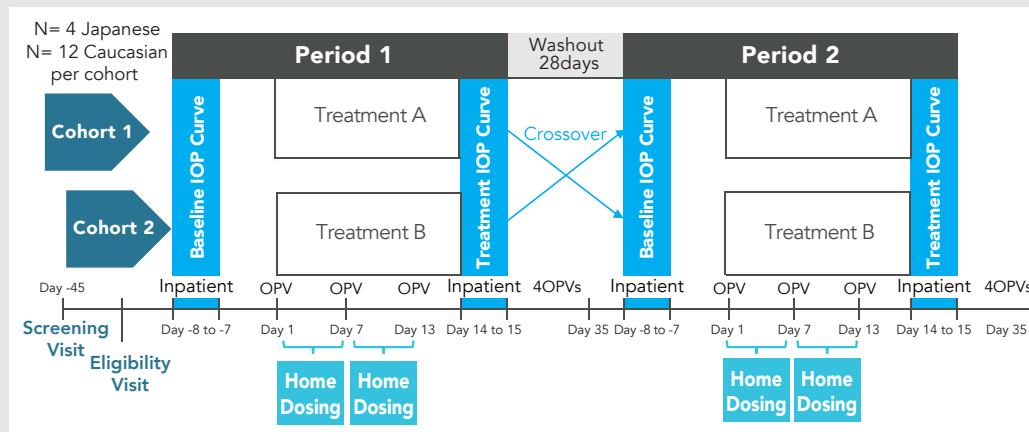
**PHASE 2
CROSSOVER STUDY
DIRUNAL IOP CURVE
PLASMA PK, SAFETY
ETHNIC SENSITIVITY**

Population: 32 Patients with glaucoma or ocular hypertension;
24 Caucasian, 8 Japanese

Enrollment Period : 45 days

Study Design:

- Screening Period of up to 45 days prior to the dosing day
- Eligibility Visit 3 to 28 days after the screening visit
- Period 1:
 - Two 24 hours inpatient visits for baseline and treatment IOP curve at WCCT Cypress CPU
 - 8 outpatient visits (OPV) at ophthalmologist's office
 - Total 10 days of home dosing (self-administration)
- 28 days washout from the last dosing of period 1
- Period 2:
 - Two 24 hours inpatient visits for baseline and treatment IOP curve at WCCT Cypress CPU
 - 8 outpatient visits (OPV) at ophthalmologist's office
 - Total 10 days of home dosing (self-administration)



Procedures Performed:

- Manifest Refraction
- BCVA
- Visual Field
- Hyperemia Assessment
- Biomicroscopy
- Corneal Staining
- Ophthalmoscopy
- Confocal Microscopy
- Sitting and Supine IOP Measurements (Serial - to compare baseline and on-treatment curves)
- Gonioscopy
- Pachymetry
- Serial PK Blood Sampling

Challenges:

- Added layer of Japanese ethnicity requirement to subset of patients, while maintaining IOP eligibility requirements for the Glaucoma or Ocular HTN criteria.
- Robust data collection: diurnal IOP at Period 1 compared to Period 2; crossover PK and safety data collected; ethnic-sensitivity data collected.

Results:

- Study conducted with two ophthalmology sites enrolling patients and centralized inpatient visits conducted at WCCT's Cypress, CA CPU.

COMPANY OVERVIEW

WCCT is a full-service, early phase contract research organization (CRO) for the pharmaceutical, biotechnology, and medical device industries. We are specialized regulatory and clinical development professionals who offer an innovative, agile and collaborative approach to every program we deliver.

- . 180+ FTEs
- . 180 bed Clinical Pharmacology Unit in Cypress, CA
- . Participated in over 1,000 trials
- . Over 600 Phase I studies
- . Strong history of First-In-Human and Pivotal BA/BE trials

Areas of Focus:

- . Ethnobridging
- . Phase 1 Healthy Volunteer
- . Infectious Disease & Vaccines
- . Ophthalmology
- . Women's Health
- . Nicotine/Tobacco

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