FIRST
IN HUMAN TRIALS
OVERVIEW

First-in-Human trials are a key step in the drug development process. This is the first opportunity for drug developers to observe or "translate" all the observations from preclinical testing in human subjects. Participants in these trials, typically healthy volunteers, face an element of risk as the ability of researchers to predict the effects of a new medicine on people is limited before it has been studied in humans.

Therefore, these trials are best conducted by an organization that understands the risks associated and keeps the safety and well-being of subjects as a first priority when designing and executing these studies.

Since 2005, WCCT has conducted over 140 First-in-Human trials at our clinical pharmacology unit in Cypress, CA. Of these, over a fifteen have resulted in FDA-approved drugs, and a dozen more are currently being developed in late stage trials.

140+
FIH STUDIES

17
APPROVED PRODUCTS

13
IN LATE STAGE DEVELOPMENT

Early development (First-in-Human) protocols have become increasingly complex over the past several years. Single and Multiple Ascending Dose protocols often include multiple objectives:

- Safety and Tolerance
- Pharmacokinetics
- Pharmacodynamics (early indicators of "on-target" or " off-target" activity relative to drug exposure utilizing specific biomarkers)
- Food effect
- Participant age, gender, or ethnicity
- Potential interactions with expected co-therapies
- Therapeutic outcome in a small panel of patients suffering the targeted illness

WCCT can help you evaluate or determine:

- Starting Dose/Maximum Recommended Starting Dose (MRSD)
- Dose escalation strategy
- Strategies for using biomarkers to assess potential on-target and off-target activities of your compound
- "Ethnic sensitivity" at the targeted therapeutic level or at all doses tested
- Potential DDIs or the effect of food

WCCT ADVANTAGES FOR FIRST-IN-HUMAN STUDIES

In-House scientific and medical writing personnel
Supports protocol development and creates clear stopping rules and terms for safety review meetings

Internal Safety Review Committee
Ensures smooth progression between cohorts as doses are increased

In-House Safety Reference Laboratory
Allows PK/Safety results to be available in under 24hrs. to inform dose escalation decisions

Ability to obtain data from biomarker evaluation
Enhances "go/no-go" decisions by determining if specific targets are reached

Robust volunteer database of over 55,000
Expedites enrollment timelines, provides access to best-fit subject population.

TO DISCUSS YOUR UPCOMING CLINICAL DEVELOPMENT PROGRAM, CALL US AT (714) 252-0770 OR E-MAIL US AT MGR@WCCT.COM

Address: 5630 Cerritos Ave, Cypress, CA 90630

SAMPLE EXPERIENCE LIST

WCCT GLOBAL
AN ALTASCIENCES COMPANY

Therapeutic Area	Drug Indication	Population	Route Of Administratoin	Goal	Enrolled
Cardiology Vascular	Transient Ischemic Attacks/Strokes	Healthy Volunteers	Intravenous	**80**	**82**
Nephrology Urology	IC/IBS	Healthy Volunteers	Intravesically	**72**	**78**
Neurology	Alzheimer's Disease	Healthy Volunteers	Oral	**68**	**83**
Gastroenterology	NAFLD NASH	Healthy Volunteers	Oral Tablet Pill	**64**	**66**
Hematology	Pyruvate Kinase	Healthy Japanese Non-Asian	Oral	**60**	**60**
Rheumatology	Osteaoarthritis	Healthy Volunteers	Topical	**60**	**63**
Ophthalmology	Glaucoma	Bilateral OHT Chronic OAG	Eye Drops	**60**	**65**
Pulmonary Respiratory	Bacterial Pneumonia	Healthy Volunteers	Nasal	**56**	**58**
Pulmonary Respiratory	Asthma	Asthmatic	Intravenous Subcutaneous	**48**	**47**
Neurology Oncology	Chemo-Induced Peripheral Neuropathy	Healthy Japanese Caucasian	Intravenous	**48**	**48**
Rheumatology	Postmenopausal Women	Postmenopausal Women	Oral	**40**	**31**
Pulmonary Respiratory	RSV	Healthy Males	Nasal	**35**	**35**
Cardiology Vascular	Thrombosis	Healthy Japanese	Oral Solution	**32**	**32**
Neurology	Alzheimer's Disease	Healthy Elderly	Oral	**30**	**29**
Infectious Diseases	Antibiotic	Healthy Elderly	Oral	**30**	**40**
Endocrinology	Diabetes Type II	Healthy Japanese	Subcutaneous	**24**	**24**
Infectious Diseases	Hepatitis C	Hepatitis C	Oral Tablet Pill	**8**	**14**
Nephrology	Chronic Kindney Disease	Renal Impaired	Intravenous	**7**	**7**
Ophthalmology	Glaucoma POAG, OHT	POAG, OHT	Eye Drops	**7**	**7**

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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