

We have highly dedicated staff with most resources having over 5 years' experience working with IHC. Our dedicated staffing group consists of over 40 resources. Our CRA and other specialty resources allow us to expand our size to support larger programs with specialized and skilled staff for the areas of interest.

IHC has well experienced CRAs and project managers in many disciplines, and we also utilize contract CRAs. We only use contractors with long standing relationships with IHC. We do not secure projects and then post CRA positions with recruitment firms in hope to adequately staff the program. Our key staff is set and dedicated and presented at the time of RFP submission to our potential client.

### **OUR PHILOSOPHY**

We do not charge out of scopes unless there are inherent changes in the study assumptions. Therefore, clients can be assured our research budget is our true budget in the vendor review process.

We also do not bait and switch proposed staffing. Some CROs involve their best staff in their bidding process to then switch in cheaper less experienced staff once the project is awarded. When IHC is awarded a study, our clients rest assured their team is experienced and dedicated to their project. Our staff does work on multiple programs, but we never assign staff to over 0.80FTE unless a single project requires full time support.

We simply ask that new clients give us an opportunity to propose our services for your project. Our references will say the same thing each time...we become a partner, we are dedicated to the end, we understand the goals and the business behind your research, sites enjoy working with us, and most importantly, we do a great job for our clients.

## **CONTACT US**

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For a full detailed description of IHC Services, please visit us on the web at w w w . i h c r e s e a r c h . c o m



## **International HealthCare**

We design, develop, and manage the entire clinical process.



## **ABOUT US**

International HealthCare (IHC) is a full-service contract research organization (CRO) and product development company providing clinical trials and regulatory services to the pharmaceutical, medical device, and biotechnology industries worldwide.

IHC is a specialty CRO that has supported clinical trials since 2001. Its owners, Dr. Peter Fratarcangelo (over 35 years industry experience) and William Tobin, MPh (over 25 years industry experience), have been partners the entire time and are intimately involved in all programs supported by our firm. Peter and Bill are intimately involved in every project IHC supports, and our mission is to provide the best service possible to our clients to build long term relationships.

IHC designs, monitors, and manages all phases of clinical trials, utilizing technology where appropriate to ensure data integrity and accelerate the clinical research process. When success is critical, experience is mandatory. International HealthCare maximizes your potential for success.

# **CLINICAL EXPERTISE**

IHC has the staff expertise necessary to manage all drug, device, and tissue trials. We have the expertise and experience to design your entire clinical program, implement, monitor and complete the studies, analyze the data, and report the results for regulatory submissions and publications.

### MEDICAL DEVICES

IHC has managed the entire clinical program of several cardiovascular medical devices from direct stenting and drug-eluting stents, spine stabilizing devices, to the development of a vascular device to treat varicose veins.

- Cardiovascular
- Imaging
- Orthopaedics
- Endovascular
- Surgical: Repair & Implants
- Tissues
- COPD

#### RX - PHASE I TO IV

IHC provides full clinical research services, regulatory strategy and submission guidance as well as full product development capability to the pharmaceutical, biotechnology and medical device industries worldwide. Examples of our clinical trial therapeutics areas:

- Cardiovascular
- Infectious Disease
- Pain Management
- Gastroenterology
- CNS
- Anti-Infectives
- Dermatology
- Diabetes
- Hepatorenal Syndrome
- Nephrology
- Opthamology
- Rhinitis Asthma, Coughs & Colds
- Rx > OTC

### OTC CONSUMER

IHC has expertise and experience in Rx > OTC Clinical Research. Our staff has designed, implemented and successfully supported the switch of over 11 Rx products to Over-the-Counter status.

## **IHC SERVICES**

IHC is a full service CRO meaning we can take a clinical study as a full turn-key project. Many of our clients prefer an array of services, but not in a full turnkey agreement. We are flexible in the type of services provided to our clients. Our contracting agreements are also tailored to our client's preferences. We are in the forefront of following new Clinical Research Guidelines and trends from the FDA.

### PROJECT MANAGEMENT

Our extensive industry experience from both a CRO and Pharma perspective will ensure your study's success and help pave the most efficient and effective clinical path for your product.

### SITE MONITORING

The IHC team of regional and in-house senior clinical research associates provides efficient site management.

### MEDICAL WRITING

Our medical writers produce clear, concise clinical reports, abstracts, publications and regulatory submission documents that are scientifically and medically accurate and written to fit the sponsor's needs.

### DATA MANAGEMENT / BIOSTATISTICS

IHC provides comprehensive biostatistical services to meet all your project needs.

### **REGULATORY AFFAIRS**

IHC regulatory strategy and compliance with FDA/ICH guidelines helps our clients bring their new products and new product claims to the market with an unparalleled success rate.

Our regulatory document and management team utilizes best industry practices (eTMF, DIA model) and applies proper GCPs and industry guidelines to ensure auditready and 483-free studies

### DSMB/CEC/IRBs/Pharmacovigilance

IHC provides and manages all services relating to trial safety review and adverse event monitoring

