CRITERIUM

Full-Service Contract Research Organization

Connect - Communicate - Control™

Our Therapeutic Expertise Includes:

Allergy/Asthma
Anti-Infectives
Bioequivalence
Cardiology
Dermatology
Devices & Delivery Systems
Endocrinology
Gastroenterology
Gerontology
Hematology
Infectious Diseases
Men's Studies
Metabolic Disease
Nephrology
Neurology
Oncology
Ophthalmology
Orthopedics
Pain Management
Pediatric Studies
Psychiatry/Psychology
Pulmonary/Respiratory
Surgery & Rehabilitation
Traumatology & Critical Care
Urology
Women's Studies
...and many more!

Clinical Trials Information Management Experts since 1991

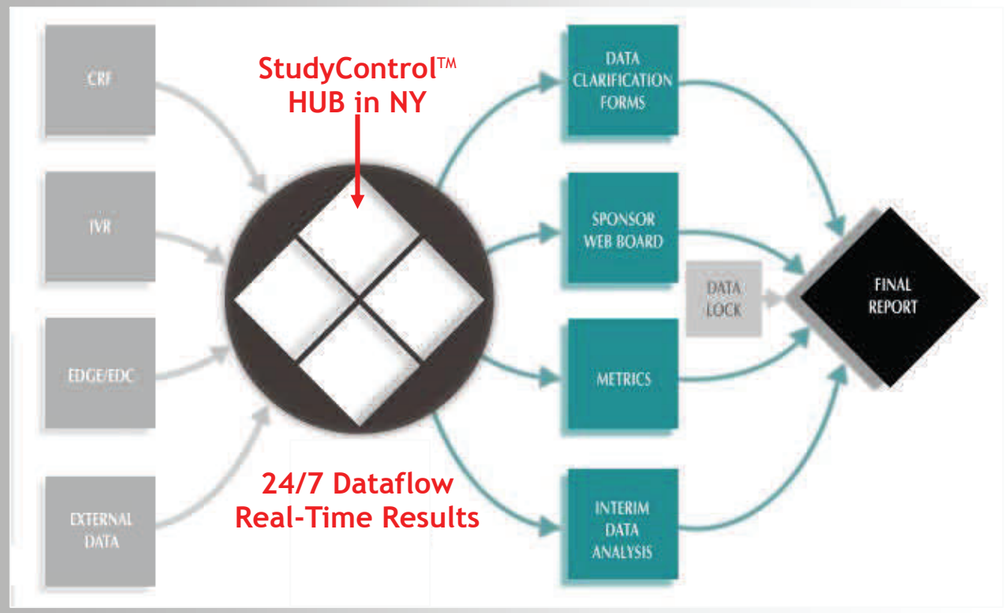
Get to Know the Experienced CRO:
CRITERIUM

- Full service - everything from initial study design to final clinical summary
- An experienced project leader is assigned to a dedicated multifunctional team
- Our CRAs have experience across all of the major therapeutic areas
- ALL have gone through GCP/ICH comprehensive training programs
- Medically qualified staff members are assigned from each therapeutic area
- Detailed & comprehensive planning, communications and action steps *are our signature*
- Clearly defined roles & responsibilities, deliverables & milestones
- Regular team updates & meetings (Criterium, Sponsor, & Vendors)
- Global Expertise, Local In-Country Connections

RESULT: Achieving or exceeding the most aggressive timelines

HOW?: *By combining the best of People, Processes & Technologies*

How do we run the BEST Clinical Trials?



StudyControl™ Seamlessly Manages Your Trial Work Flow

START with: Highly experienced data, information management and technology teams
ADD in: Clinical trial work flow managed via StudyControl™:

- Integrates data, systems and processes:
  IVRS, EDC, Fax-scanned forms/CRF, and paper forms *(if/when necessary)*
- Operates through a secured VPN
- Designed to meet high-level regulatory compliance requirements
- Can accommodate any reporting or organizational need
- Highly flexible - sets up fast - easy to use

RESULT:
A *complete information management package* with **significant time and cost savings.**

Our Service Offerings are Extensive

CRITERIUM's Clinical Trial Service Matrix ACROSS ALL PHASES					
Phase I	Phase II	Phase III	Registration/Ph IIIb	Launch	Phase IV
Protocol Design & Development					
Project & Data Management					
CRF Design & Distribution					
Site Solicitation & Qualification					
Study Monitoring: Clinical, Medical & Safety					
Translational Research					
Trial Rescue Services					
Remote Management Tools					
EDC - Electronic Data Capture					
Data & Report Management					
Biostatistics & Analysis					
Risk Management					
BE/TE - Bioequivalence/Therapeutic Equivalence Studies					
IVRS & IWRS - *PLUS* - ePRO & Patient Diaries					
Report Writing					
MedDRA & WHO Drug Coding					
CTM Management					
Regulatory Consulting					
Special Assessments					
Phase I	Phase II	Phase III	Registration/Ph IIIb	Launch	Phase IV

It's the Details that keep our Trials Efficient

Criterium Smart CRFs
- Electronic or paper
- Fields are preprogrammed and fed directly into StudyControl™
- Integrated with other data sources (ECG, LAB, IVR)
- Real time, *right from study start-up*

Criterium IVR & IWR since 1991
- Uses phone as primary method of documenting patient reported outcomes (ePRO)
- Patients need a simple and reliable way to report their information - *while it's fresh in their minds*
- Sponsors have access to the most up-to-date patient data 24/7
- Manage recruitment & patient screening
- Registration & randomization
- Routine drug supply & inventory control
- Automated data alerts & checks

Criterium EDGE —
Electronic Data Global Entry
- Maximizes worldwide data collection
- Information management in real time
- Fewer data entry errors & site queries
- *Works even where the local infrastructure does not support direct EDC entry*
- EDGE uses our Smart CRFs
- Integrates directly with data from field sites using EDC

External Data —
ECG and Lab Reports
- StudyControl™ system incorporates external data and documents
- Works with Labs, ECG, and Imaging service providers

Data Clarification Forms
- Generated within StudyControl™ *- from the beginning of the study*
- Continuously integrates, queries, and cleans all the data at all stages
- Reduces field monitoring costs
- Maintains aggressive study schedules
- Manages external data source providers

Sponsor Web Board
- Customized Web board stores and organizes data
- Deliver and view up-to-the-minute reports - *anywhere in the world*
- See current, comprehensive information on ALL aspects of study progress
- Respond to incoming data, optimize progress and efficiency of the study
- Resolve potential issues

Metrics & Interim Data Analysis
- Customized reports developed and transmitted during study
- Advises about potential mid-course corrections
- Implements real-time data
- Makes interim analysis *during the trial* fast and easy

Clinical Liaisons/In-House Monitors
"Changing the Field Monitor's Role"
- Clean and correct data before the field monitor makes site visit
- Streamlines the CRA's on-site role
- Troubleshoot patient enrollment and source documents
- Frees field monitors to assist with critical site management issues
- Reduces the number of days to complete on-site queries
- Trims the number of site visits
- Decreases days needed in the field
- Identify potential problems - *before they arise*
- Reduces the cost of field monitoring per patient by as much as half *(when compared with traditional monitoring)*

CRITERIUM Clinical Research INDIA Pvt Ltd

Welcome!

- Criterium India provides a complete package – from study initiation to final study report
- Utilizing Criterium's services is a superlative choice for your compound
- At Criterium India we provide you with competitive pricing

- Criterium staff is compliant with SOPs, ICH-GCP and regulatory requirements
- We at Criterium are committed to provide you with Excellence and Quality Service
- Criterium India provides expert consultation on all aspects of your comprehensive projects
- Criterium India has associations with major vendors
- We provide a customized collaboration tailored to bring complete customer satisfaction

RESULT: Achieving or exceeding the most aggressive timelines

HOW?: *By combining the best of People, Processes & Technologies*

The Criterium Connection: India-to-USA

DM in New York (HQ)

CRF data entry and query generation are completed over a day-night cycle between the USA HQ and India, in a maximum of 48 hours. From time of initial completion when the CRF is sent via email/fax to USA DM, it is processed during the day there, while it is still night in India. Thus the cycle for response is shortened because of global time savings.

IXR in Florida

We provide IVR (Interactive Voice Response) services where we integrate IWR (Interactive Web Reporting) services and IVRS in a unified database for 24/7 real-time interaction with the callers – sites *and* patients!

Faster DM process:

Site (India) sends CRF to DM (US)

DM (US) processes CRF and send queries to site

Example of how IVR works: IVR applications ask the patients if they have experienced any adverse events. If they answer yes, a fax or email goes to the site to request follow up with the patients to determine the exact description of the AE. **Faster workflow = faster AE resolution.**

Our India In-Country Experience: Since 2005

Indication*	Phase	Sites	Patients
Head and Neck Cancer	II/III	21	197
Diarrhea	III	6	32
HIV	PK	11	35
Gastric and gastro-esophageal cancer	II B	8	44
Traveler's Diarrhea	III	14	244
BA/BE	I	3	24-48
Gastric Cancer	III	60	740
Parkinson's Disease	III	18	91
Seizures	II	8	41
Bi-Polar Disorder	III	49	321
Anxiety, Depression, Schizophrenia, Bipolar Disorder	I-III	>100	>800
Thrombosis	III	60	740

**Partial list of studies, we also have global expertise in other indications: Asthma & Allergy, Cardiology, Dermatology, Infectious Disease, Medical Devices, Urology*

It's a Global Team with a Local base

Project Management & Monitoring

- Criterium India brings to the table extensive experience in various types of studies
- Criterium India monitors understand that while site selection is a key to executing a successful study, timely patient enrollment and valid clinical data are also critical to the results of each study
- Criterium India has shown precise and proven aptitude to accelerate vital processes
- We have a defined Organizational Structure and Operating Ethos under an established leadership
- Criterium India integrates with global counterparts and brings international work experience to a sponsor
- Criterium India staff are located in major cities
- Our proactive project management team utilizes risk-based management practices to identify and assess risks

Site Database / Site Management

- Criterium India has a large investigator database across various therapeutic areas
- At Criterium India we maintain a strong relationship with Investigative sites across all 5 regions (E,W,N,S,C) inclusive of government hospitals, private clinics and recognized institutes
- We have a thorough understanding of local customs and work diligently with Investigators for meticulous submissions and approvals
- Criterium India motivates sites to achieve their monthly patient recruitment and retention, using various methods: advertising, GP's referrals, and other channels
- At Criterium India we aid in providing shorter recruitment timelines and higher patient compliance

Regulatory Support

- Criterium India local staff manage the complete regulatory submission process along with experienced regulatory support
- Criterium India ensures timely reporting of all safety events during the progress of the study as per the updated regulatory requirements

Training & Development

- Criterium India maintains ongoing training for updated regulatory, ICH-GCP, and SOPs of its skilled personnel

Business Development

- We have expanded and relocated! Our NEW offices in India are: 701 7th Floor, Tower 1, Montreal Business Center, Survey No. 272, Baner Road, Pune 411045 ***Come Visit Us!***

Innovative
Clinical Research
Solutions
- Since 1991 -

Get To Know Us!

Where do you go from here?	
Our **Therapeutic Experience:**	http://www.criteriuminc.com/expertise.php
Our **ONCOLOGY Consortia:**	http://www.criteriuminc.com/occ.php
Our **Trial Services:**	http://www.criteriuminc.com/services.php
Our *(Partial)* **Client List:**	http://www.criteriuminc.com/part_client.php
Our **Customer's Comments:**	http://www.criteriuminc.com/testimonials.php
Our **Client Services List:**	http://www.criteriuminc.com/client_services.php
Our **Case Study** examples:	http://www.criteriuminc.com/case_studies.php
We invite you to join our list of satisfied clients!	

"At Criterium, Connect◆Communicate◆Control™, reflects the commitment of our people to providing real-time information, processes, and technologies. Our high-trust relationships result in high-performing teams."
-John Hudak, MBA, Founder, CEO

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