



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

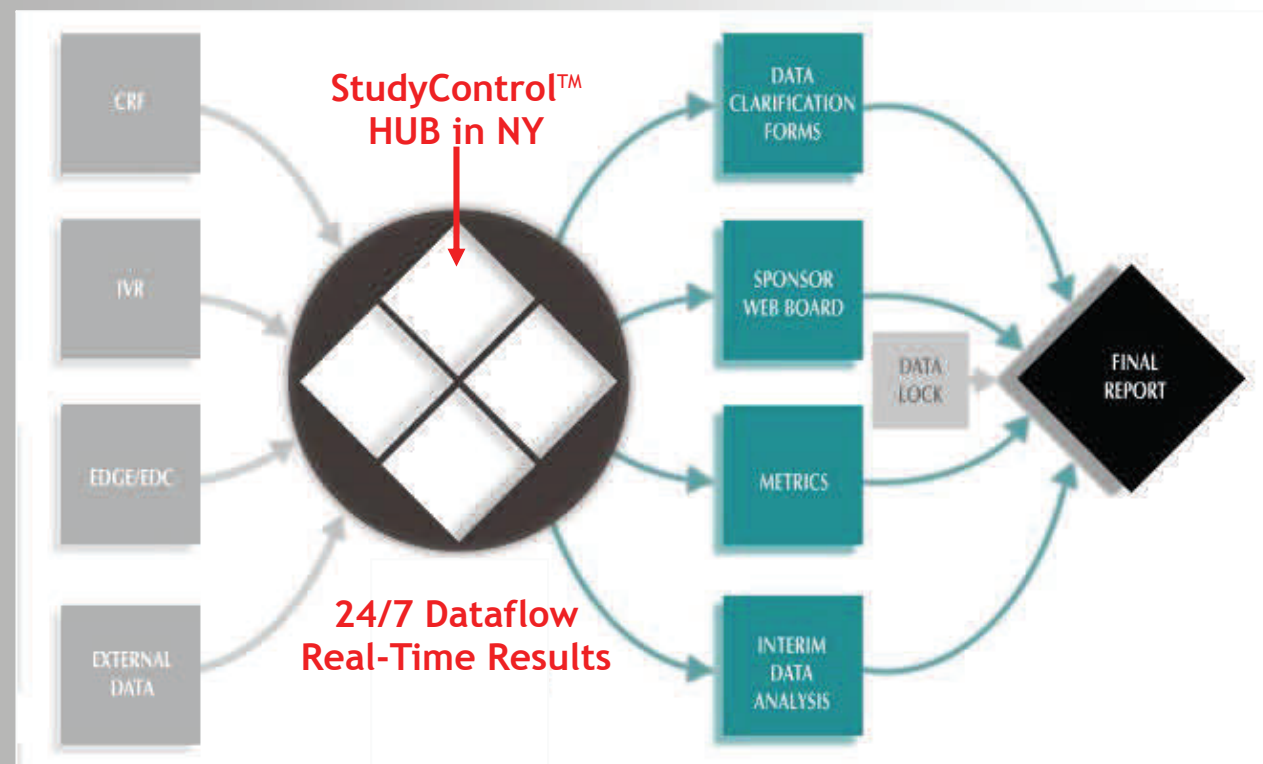
- ❖ Full service - everything from initial study design to final clinical summary
- ❖ An experienced project leader is assigned to a dedicated multifunctional team
- ❖ Our CRAs have experience across all of the major therapeutic areas
- ❖ ALL have gone through GCP/ICH comprehensive training programs
- ❖ 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 (Criterion, 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

Criterion 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*

Criterion 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

Criterion 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)*



**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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