

## Connect □ Communicate □ Control™

*Our Therapeutic Expertise Includes:*

- Allergy
- Anti-Infectives
- Bioequivalence
- Cardiology
- Critical Care
- Dermatology
- Devices & Delivery Systems
- Gastroenterology
- Hematology
- Infectious Diseases
- Men's Studies
- Metabolic Disease
- Oncology
- Orthopedics
- Ophthalmology
- Pain Management
- Respiratory
- Surgery
- Urology
- Women's Studies
- ...and more!*

## Get to Know the Experienced CRO: CRITERIUM

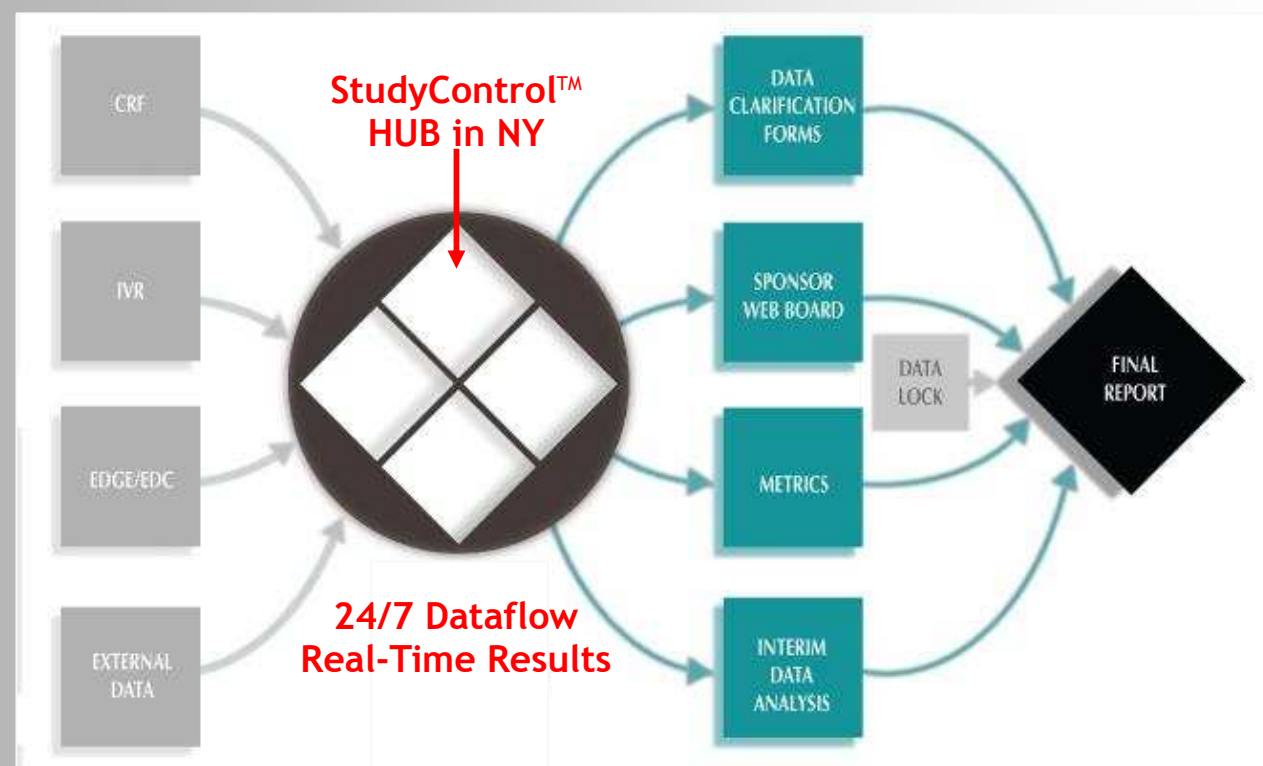
- ❖ Full service - everything from initial study design to final clinical summary
- ❖ An experienced project leader is assigned to a dedicated multifunctional team
- ❖ Our CRAs have experience across all of the major therapeutic areas
- ❖ ALL have gone through GCP/ICH comprehensive training programs
- ❖ 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 Drug Development Clinical Trial Service Matrix					
Phase I	Phase II	Phase III	Registration / Ph IIIb	Launch	Phase IV
Protocol Development					
CRF Design & Distribution					
Site Solicitation & Qualification					
Study Monitoring					
Remote Management Tools					
EDC Electronic Data Capture					
Data & Report Management					
Statistical Analysis					
Risk Management					
BE/TE Bioequivalence/Therapeutic Equivalence Studies					
IVR & IWR					
Report Writing					
MedDRA & WHO Drug Coding					
CTM Management					
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 the start of the study*

### Criterion IVR & IWR - ePRO 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 and information management in real time
- ❖ Fewer data entry errors
- ❖ Fewer 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)*

# Get To Know Us!

## Where do you go from here?

Our Therapeutic Experience:	<a href="http://www.criteriuminc.com/expertise.php">http://www.criteriuminc.com/expertise.php</a>
Our Trial Services:	<a href="http://www.criteriuminc.com/services.php">http://www.criteriuminc.com/services.php</a>
Our (Partial) Client List:	<a href="http://www.criteriuminc.com/part_client.php">http://www.criteriuminc.com/part_client.php</a>
Our Customer's Comments:	<a href="http://www.criteriuminc.com/testimonials.php">http://www.criteriuminc.com/testimonials.php</a>
Our Client Services List:	<a href="http://www.criteriuminc.com/client_services.php">http://www.criteriuminc.com/client_services.php</a>
Our Case Study examples:	<a href="http://www.criteriuminc.com/case_studies.php">http://www.criteriuminc.com/case_studies.php</a>

**We invite you to join our list of happy 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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