

CRITERIUM

CONNECT • COMMUNICATE • CONTROL™



**Innovative
Clinical Research
Solutions**
- Since 1991 -

GET TO KNOW US!

NEW YORK / CALIFORNIA / FLORIDA / SOUTH AFRICA / EU / INDIA / RUSSIA / ISRAEL / CANADA

www.criteriuminc.com





www.criteriuminc.com

CRITERIUM



1. (n.) **crit**erium, or **crit**, is a bike race held on a short course (usually less than 5 km), often run on closed-off city center streets; the most common type of bicycle racing in the continental United States

2. (n.) **Criterium, Inc.**, is the *original agile* CRO that knows how to maneuver and manage your clinical trial cycles to the finish line; information management experts

Success in road criteriums, as in clinical trials, requires a mix of good technical skills -- in particular, the ability to “corner smoothly” while “holding the line” on the road, as well as **moving rapidly** and **sharply** through the course. It requires riding safely with a large group on a short circuit – plus exceptional **endurance** and the **resiliency** to accelerate hard from tight corners – all with the **flexibility and performance of a true leader.**

Criterium CRO competes like a fine tuned athlete, with the stamina and determination to win every time.

Ride with us to the finish line!



Our goal is to provide world-class clinical development services.

By flattening our business operations, our staff members and clients around the world are integrated into the process using Criterium-developed technology.

John Hudak, MBA
President and Founder





■ Red: Current offices with numerous additional regional monitoring locations.

● Yellow: Planned offices and local representation in EU, Australia, New Zealand and Argentina.

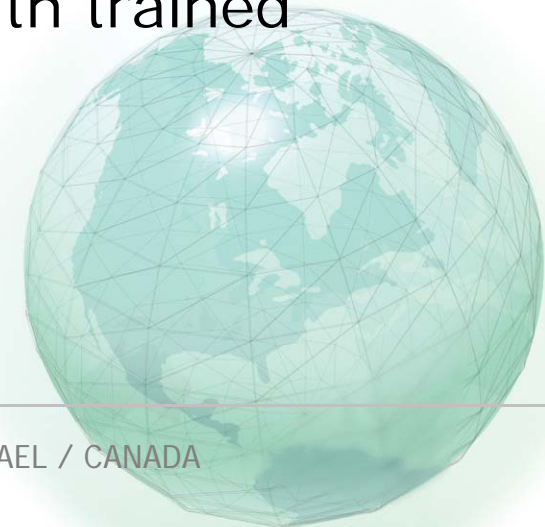


Full-Service Contract Research Organization

- Trial Rescue Services
- Project & Data Management
- Translational Research
- Biostatistics
- Site Selection & Management
- Protocol Design & Consulting
- Clinical & Medical Monitoring
- CRF Design
- IVR / IWR
- Fax & Electronic Data Capture
- Medical Writing
- Safety Monitoring
- Regulatory Consulting



- **Criterion technology** ...to collect data in real-time
- **Criterion workflow** ...to manage the data and provide information in real-time
- **Criterion staff** ...who are committed to the process and the project (low turnover)
- **Criterion manages** ...the sites remotely, with trained staff who monitor the data every day



Criterion services include a broad range of **clinical development capabilities**, **integrated advanced technologies**, and **regulatory affairs consulting**:

Product Development Expertise

- Phase I – IV, including post marketing and pharmacovigilance studies
- Translational Science methodologies
- Study monitoring
- Product development
- Regulatory affairs, agency and IND submissions
- Strategic compliance and risk management
- BE/TE Studies
- Special Assessments

Technology Expertise

- CRF Design and Development
- EDC Integration
- Clinical Trial Management Systems (CTMS)
- Interactive Voice and Web Response Systems (IVRS/IWRS)
- Remote Management Tools
- Integration Services
- MEDRA & WHO Coding

Process Expertise

- Protocol Development
- Project management
- Site solicitation, qualification & management
- Patient and investigator recruitment, grant management
- Site monitoring
- Data & Report management
- Biostatistics Medical Services and Analysis, Final CSR
- Risk management

Communication Expertise

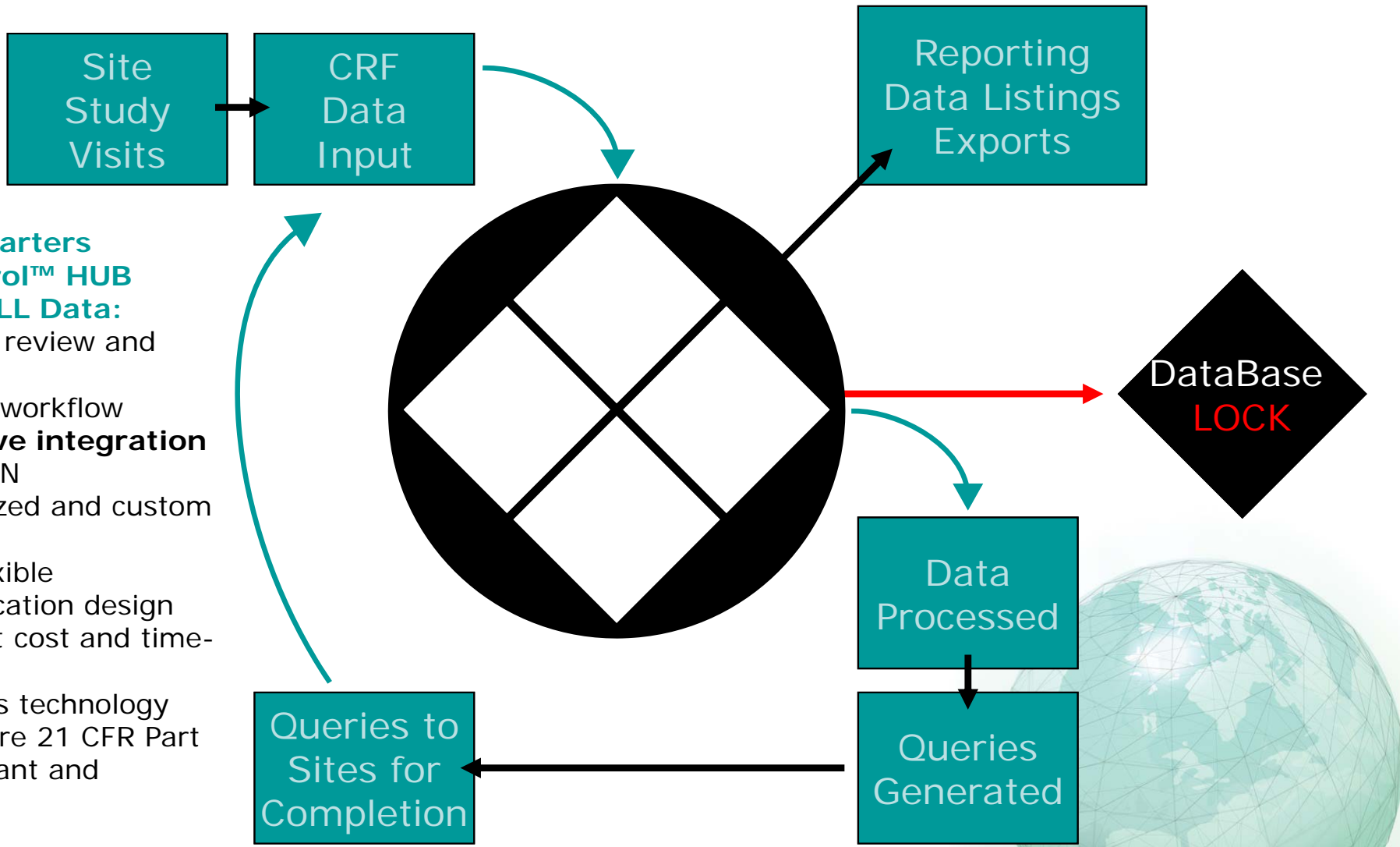
- Meetings, events, and exhibits
- Publications



Allergy	Perennial Allergic Rhinitis, Seasonal Allergic Rhinitis, Bacterial Sinusitis, Allergic Conjunctivitis
Cardiovascular	CHF, Hypertension, Arrhythmias, Mortality, Angina, Atherosclerosis, post-CABG
CNS	Alzheimer's Disease, Anxiety, Depression, Multiple Sclerosis, Chronic Fatigue Syndrome, Schizophrenia, Bipolar Disease, Panic Disorder
Dermatology	Cosmetic, Retinoic Acid, Decubitis Ulcer, Artificial Skin, Psoriasis, Tinea Versicolor, Acne, Tinea Pedis, Actinic Keratosis, Wound Healing, Onychomycosis, Rosacea, Eczema, Dermatitis, Infectious Diseases of the Skin, Nevi and Seborrheic Keratosis
Delivery	Inhalation, Intranasal, Buccal, Trans dermal, Intravenous, Intra- Thecal, Oral, , Electroporation Device for the Delivery of Plasmids, TNS
Gastroenterology	Crohn's Disease, Diarrhea, Traveler's Diarrhea, Ulcerative Colitis, Duodenal Ulcer, Functional Dyspepsia, Irritable Bowel Syndrome with Constipation, Heartburn, Esophagitis, Gastric Ulcer, Fabry Disease, Gastric Cancer, Irritable Bowel Traveler's Diarrhea, Constipation
Hematology	Anemia - Thermal injury, Anemia - Cancer treatments, Anti Coagulant for central line, CABG, Factor 8 Def, Hypercholesteremia, Hypercholesteremia/Hyperlipidemia, Malignant Melanoma, Acute Myeloid Leukemia, Home Infusion Treatment, Hemophilia & Hemophilia Factor VIII, Von Willebrand's Disease, Thromboembolism in Gastric Cancer, Sickle Cell Anemia, Angioedema
HIV/Infectious Disease	HIV, AIDS, LRTI, Pediatric Pneumonia, Chronic Bronchitis, SSSI, UTI, Hepatitis A, B, and C, Otitis Media, Bacterial Vaginosis, Malaria, Necrotizing Fasciitis, Fungal Infections – Tinea Pedis, Tinea Versicolor, Osteomyelitis, Anemia, Sepsis, Skin and Soft Tissue Infections
Immunology	Auto-Immune Disease (Rheumatoid Arthritis, Osteoarthritis, Crohn's Disease)
Internal Medicine	Crohn's Diseases, Osteoarthritis, Rheumatoid Arthritis, Ulcerative Colitis, Anemia, Erythropoietin, Iron Supplements, Vitamins
Media	Tablets, Capsules, Solutions, Sterile Solutions, Gels, Creams, Patches, Sublingual
Medical Devices	Stents, Bulking Agents for Incontinence, Bladder Retraining Device, Bladder Warming Device, Artificial Skin for Wounds and Ulcers, Nebulizers for Delivery of Drug to Lung, Lens Replacement for Cataracts, Diagnostic Equipment Evaluation, Bulking Agent for Wrinkles, Transcutaneous Nerve Stimulators (TNS) for Pain, TNS for urge incontinence (OAB) , Electroporation Device for Delivery of plasmids

Men's Studies	Erectile Dysfunction, Hormone Replacement Therapy, Benign Prostatic Hypertrophy (BPH), Transurethral resection of the prostate (TURP), Urinary Incontinence, Quality of Life
Metabolic Disease	Diabetes, Hypercholesteremia, Hyperlipidemia
Oncology	Solid Tumor and Hematological Cancers; Pancreatic, Breast, Skin and Gastric Cancer, Multiple Myeloma, AL Amyloidosis, AML, ALL, CLL, Actinic Keratosis and Squamous Cell Carcinoma, Malignant Melanoma, Quality of Life (E.g., SF-36, EORTC), Thrombosis Associated with Chemotherapy, Genital Warts, Electroporation Device for the Delivery of Plasmids (Melanoma), Renal, Pituitary, Head and Neck, Colon, TNF Factors, Anti-Coagulants, Epoetin Alfa, G-CSF, GM-CSF, Chemotherapy, Pharmaco-genomic Therapy, ECOG Performance Status Scales, Translational Research
Ophthalmology	Lens Replacement, Secondary Cataracts, Intraocular Lens, Myopia / Hyperopia- Implanted Contact Lens (ICL), Allergic Conjunctivitis Anti-Allergy Therapy, Open Angle Glaucoma (Collagen Glaucoma Drainage Device), Open Angle Glaucoma Support, Aphakia (IOL with anti-infective treatment), Glaucoma Diagnosis, Age-Related Macular Degeneration (ADM)
Orthopedic	Median sternotomy closure (device), Iliac crest bone graft harvest sites (device)
Pain Management	Narcotic, Non-narcotic, Acute and Chronic Pain, Post-operative Pain, Fibromyalgia, Wisdom Tooth Extraction, Low Back Pain, Osteoarthritis, Rheumatoid Arthritis, Malignant and Non-Malignant Pain, Cancer Pain, Headache Pain, Migraine, Transcutaneous Nerve Stimulation
Respiratory	Mild, Moderate, and Severe Pediatric and Adult Asthma; Community Acquired Pneumonia, Chronic Obstructive Pulmonary Disease (COPD), Cystic Fibrosis, Respiratory Tract Infections
Transplantation	Kidney
Urology	Urinary Incontinence, Urge Incontinence, Stress Incontinence, Stents, Erectile Dysfunction, Chronic Renal Failure
Vaccines	HIV, Plasmapheresis, Influenza, Rotavirus, HPV
Women's Studies	Premature Labor and Delivery, Oral Contraception, Hormone Replacement Therapy, Bleeding Disorders, Stress and Urinary Urge Incontinence, Osteoporosis, In Vitro Fertilization

- NY Headquarters
StudyControl™ HUB
Receives ALL Data:**
- 48 hrs. to review and query
 - Seamless workflow
 - **Innovative integration**
 - Secure VPN
 - Standardized and custom reporting
 - Highly flexible
 - Fast application design
 - Significant cost and time-savings
 - Criterion's technology systems are 21 CFR Part 11 compliant and validated



The IVRS Services Suite At-A-Glance

Customer Self Service
Web Based
Application Templates

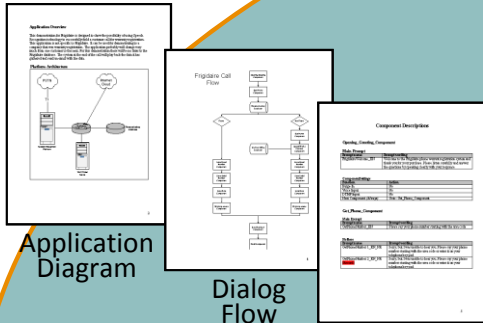


Client
Web
access



Internet
Intra/Extranet
Cloud

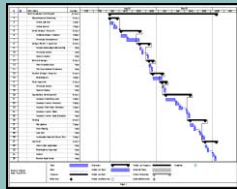
Advanced Application
Development Process



Application
Diagram

Dialog
Flow

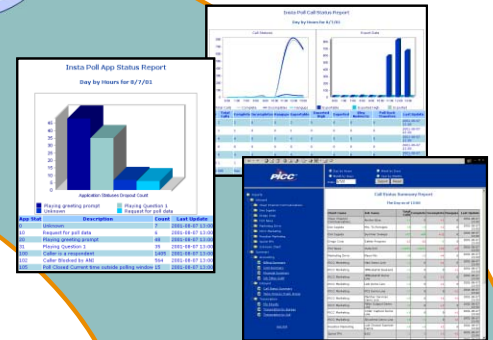
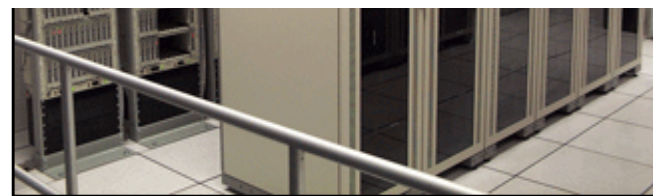
Voice Prompts
and Speech Reco
Vocabularies



Project
Plan



24/7 Continuous Workflow



Real Time Results Reporting



Automated System for
Alerts & Alarms



24 hour
Technical
Help Desk



Secure Backup &
Diesel Generator

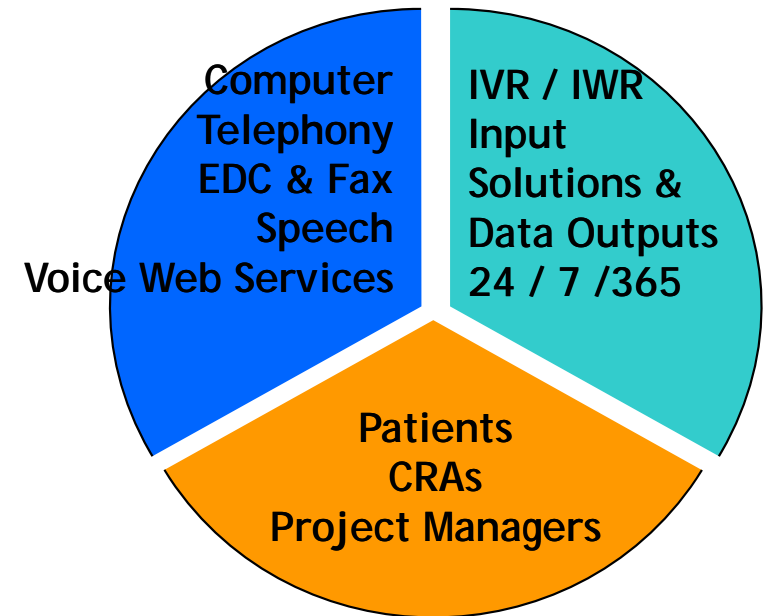
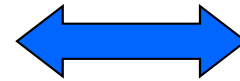
Call Center
Live Agent
Backup



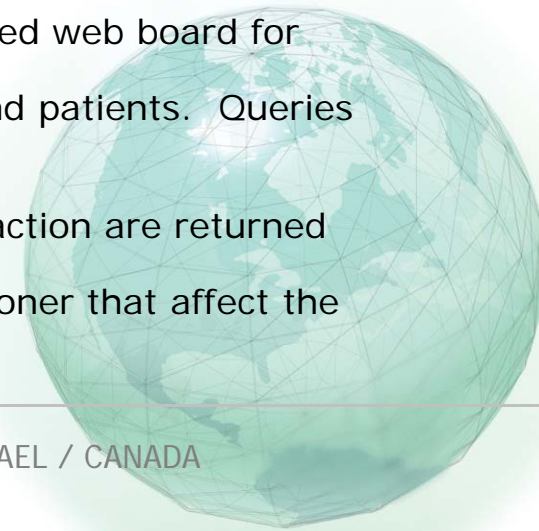
Complete Workflow Integration



Phone, PDA or any computer input

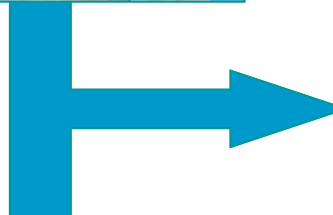


- Sites/pharmacies register patients.
- Sites fax completed Faxforms with patient information.
- The phone/computer allows patients and sites to input diary information.
- Centralized computers receive and integrate IVR and FAX input.
- These data are compiled into a database and output onto the internet based web board for viewing and analysis – 24/7/365
- Central project managers review and interpret data received from sites and patients. Queries go directly back to the sites.
- CRAs send corrections and reports back to the system.
- Study data are used to manage CRAs' visit schedules. Queries requiring action are returned directly to the sites.
- Sites and sponsors can respond to the data faster, and make decisions sooner that affect the outcome of a successful trial





Any phone, any time, any place, ANY PATIENT



Any computer, any time, any place

Company Logo Here

[HOME](#) [LOGOUT](#) [HELP](#)

Study Identification: NCC-1701 User ID: hudakjm01

Search Criteria :

Dates from to
Patient Status

Patients: to
Report Type

Sites:

Patient Info

Patient : 990041
DOB (month/year) : May 1958
Registration Date : Nov 8 2007 2:55PM
Status : Active

24/7 Real-Time Data with
Easy-Access Web Board Reporting
For Sponsors

Site	Patient ID	Call Time	Call Time	Patient Status	Question 1	Question 2	Question 3	Question 4	Exported EDC
990	990041	11/10/2007	9:01:00 PM	Active	No				11/11/07
990	990041	11/12/2007	9:43:00 PM	Active	No				11/13/07
990	990041	11/13/2007	10:31:00 PM	Active	Yes	2	Yes	3	11/14/07
990	990041	11/18/2007	8:41:00 PM	Active	No				11/19/07
990	990041	11/19/2007	9:46:00 PM	Active	No				11/20/07
990	990041	11/25/2007	9:36:00 PM	Active	No				11/26/07

Many Customizable Reports of IVRS

“Custom and standard reports can be accessed by anyone, anytime, anywhere via web-based reporting.”

IVR Menu of Available REPORTS

Click on any report to see more information:

STANDARD REPORTS - IVR

- Randomization Report - Per Site
- Study at a Glance Report**
- Site Summary Report
- Drug Shipment Report Summary
- Drug Shipment By Visit
- Blinded Drug Report - Total Drug at Each Site (Available/Shipped/Damaged/Expired)
- Unblinded Drug Report - Total Drug A and/or Drug B (Available/Shipped/Damaged/Expired)
- Chart Outcomes in Graph

CUSTOM REPORTS – Client

- User Summary Report - All Permissions and Access Logs
- Projects Report - List of all Projects
- Estimated Visit Projection Report
- KIP Report - View of Indicators Per Site
- Drug Reports - Monitor Only Access
- Generate Labels for all Drug that is Shipped to CDD
- Projected Drug Use Report (Per Site)
- Drug Tracking Report - In-Transit/Delivered/Returned
- Drug Discontinuation Report
- Drug Auto Replenish Report
- Emergency Unblinded Report



Site Name	Status	Start Date	End Date	Phase	Notes
Site 001	Active	2012-01-01	2012-03-31	Phase 1	
Site 002	Active	2012-01-01	2012-03-31	Phase 1	

Site Name	Phase	Start Date	End Date	Drug A	Drug B
Site 001	Phase 1	2012-01-01	2012-03-31	100	0
Site 002	Phase 1	2012-01-01	2012-03-31	100	0

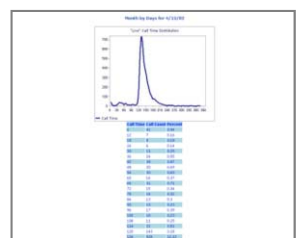
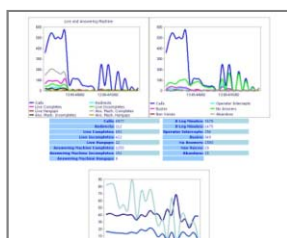
Site Name	Phase	Start Date	End Date	Drug A	Drug B	Drug C
Site 001	Phase 1	2012-01-01	2012-03-31	100	0	0
Site 002	Phase 1	2012-01-01	2012-03-31	100	0	0



Site ID	Client Name	Job Name	Status	A Log Rounding Type	A Log Lev	A Log Rounding	B Log Rounding Type	B Log Lev	B Log Rounding	Complete Markup	Incomplete Markup	Markup	Target Lev	Target Lev	Trans Self Multiplier
0001	Don Jagoda	Don Jagoda	Active	30-R	0.00	0.00	30-R	0.00	0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	0
0002	Don Jagoda	Don Jagoda	Active	30-R	\$0.00	\$0.00	30-R	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.20	\$0.11	1.50



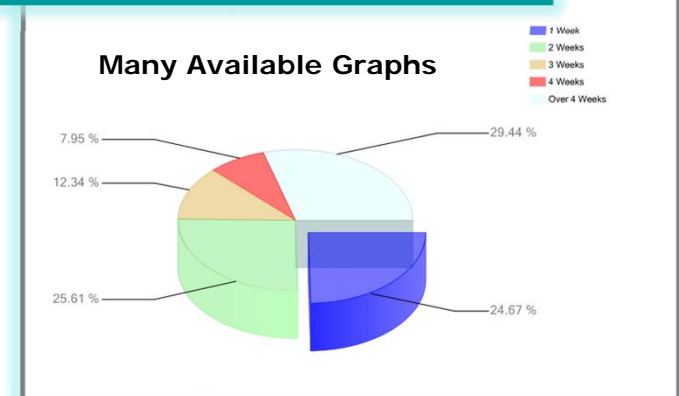
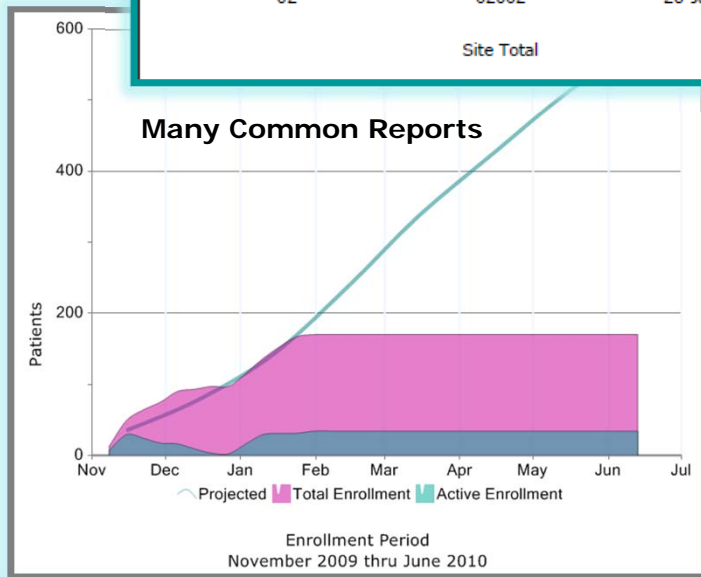
Site Name	Phase	Start Date	End Date	Drug A	Drug B	Drug C
Site 001	Phase 1	2012-01-01	2012-03-31	100	0	0
Site 002	Phase 1	2012-01-01	2012-03-31	100	0	0



Site Name	Phase	Start Date	End Date	Drug A	Drug B	Drug C
Site 001	Phase 1	2012-01-01	2012-03-31	100	0	0
Site 002	Phase 1	2012-01-01	2012-03-31	100	0	0

Subject Enrollment Status						
Site 01						
Site	Patient	Registered	Screen Fail	Randomized <i>*Projected</i>	Early Discontinuation	Completed Study <i>*Projected</i>
01	01001	04-Dec-2009		04-Dec-2009	08-Dec-2009	
01	01002	08-Jan-2010		08-Jan-2010		25-Jan-2010
01	01003	26-Jan-2010		02-Feb-2010		
01	01004	28-Jan-2010		04-Feb-2010		24-Feb-2010
	Site Total	4	0	2	1	1
Site 02						
Site	Patient	Registered	Screen Fail	Randomized <i>*Projected</i>	Early Discontinuation	Completed Study <i>*Projected</i>
02	02001	18-Jan-2010		18-Jan-2010		
02	02002	26-Jan-2010		02-Feb-2010		
	Site Total	2	0	1	0	0

Completed Study: 11
Currently Active: 235



“The IVR system not only collects data in real-time but allows the use of the information for real-time decision-making.”

CTSM / IVR Drug Inventory Applications SOLVE these 3 major issues:

Labor Intensive Process - Short Lead Times - Limited Trial Supply

Automated Randomization and Trial Supply Management logistics are managed using a central computer accessed via telephone, (IVR/Interactive Voice Response) and web board (IWR/Interactive Web Response) interfaces.

IVR provides randomization methods supported by experienced industry statisticians:

- static blocked lists
- stratification
- custom algorithms

Key IVR Features Supporting CTSM

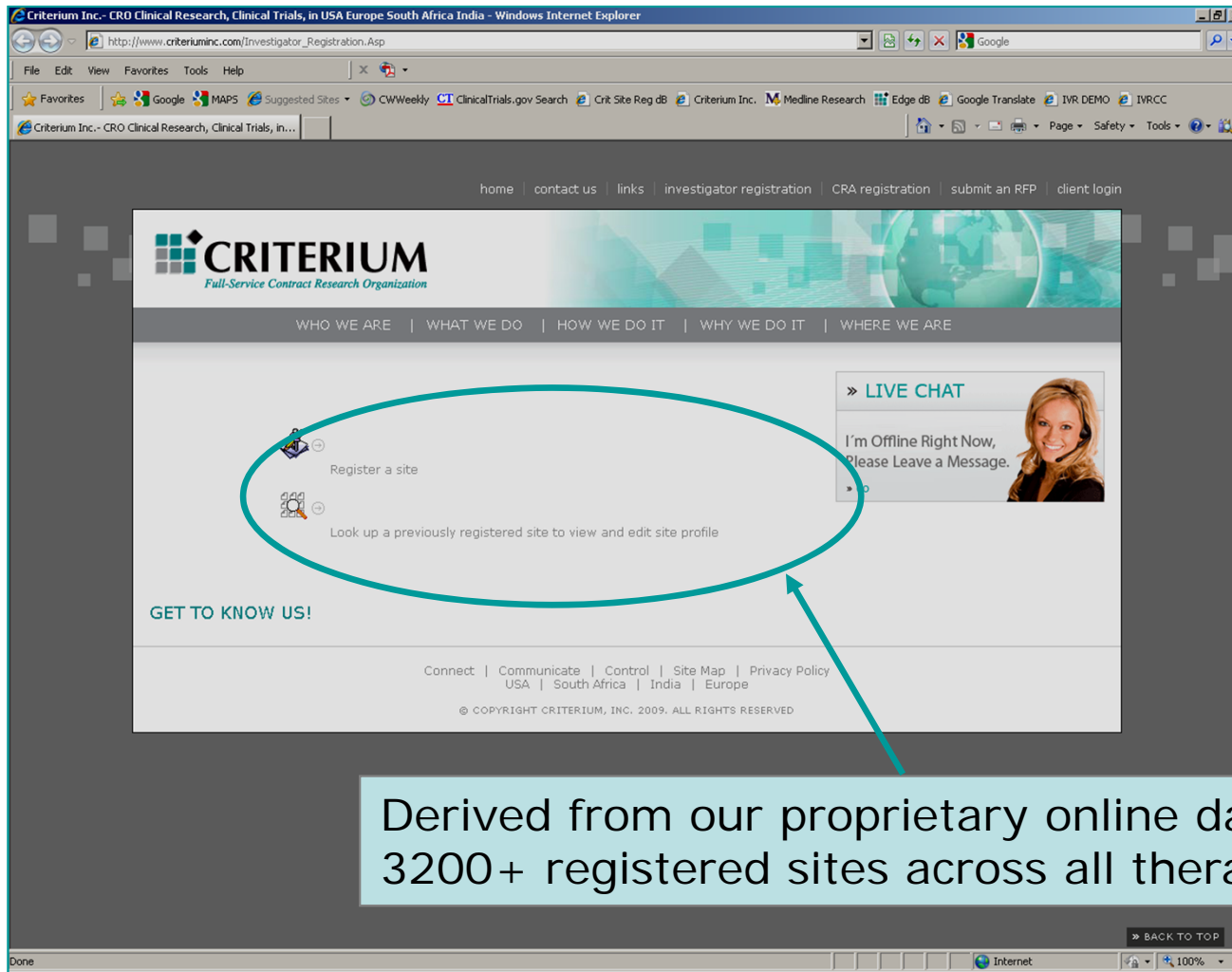
- Extensive range of randomization methods
- Automated inventory control
- Dispensing and titration management
- Comprehensive management of adaptive trials
- Emergency code break
- Real-time study recruitment and supply location/status reporting
- 24/7/365 toll-free availability
- 24/7 support



Criterion's Investigator Site Database

Investigative Sites:

Sites are identified and summarized per project requirements



CRITERIUM
Full-Service Contract Research Organization

WHO WE ARE | WHAT WE DO | HOW WE DO IT | WHY WE DO IT | WHERE WE ARE

Register a site

Look up a previously registered site to view and edit site profile

GET TO KNOW US!

Connect | Communicate | Control | Site Map | Privacy Policy
USA | South Africa | India | Europe

© COPYRIGHT CRITERIUM, INC. 2009. ALL RIGHTS RESERVED

Derived from our proprietary online database of 3200+ registered sites across all therapeutic areas

Why Should a Sponsor Consider Criterium?

- **Criterium** can deliver services on time, within budget, done right:

We are serious about customer satisfaction

- We specifically **reduce unnecessary delays** to marketplace by paying *incredible* attention to all details:

http://www.criteriuminc.com/case_studies.php

- We are expanding our reach around the world and into a wider **range of therapeutic areas**:

http://www.criteriuminc.com/client_services.php

- Our previous collaborations have **proven to lower the risk** for our clients:

<http://www.criteriuminc.com/testimonials.php>

- Our partnerships and client base are growing stronger as partners see **how well we can provide services** to them:

http://www.criteriuminc.com/part_client.php



Thank You for Visiting!

Please contact us to get an **RFP** or a **competitive bid** on
your next project...
and see what **we** can do for you that other CRO's *can't*...

Or... download our brochure
for even more information:
[Criterion Brochure Online](#)

We look forward to working with you!





CRITERIUM

Full-Service Contract Research Organization

Celebrating 20 Years
of Creative Clinical Research 1991-2011



Connect ❖ Communicate ❖ Control

GET TO KNOW US!