## IT Solutions

Your information technology directory

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Count on the Applied Clinical Trials 2004 IT Solutions Directory to learn who provides applications for clinical trials—and how to reach them. To find the right tools for your trials, search the categorized directory.
**Aris Global**

**ARIS**

The most advanced software for pharmacovigilance and global regulatory compliance enables the collection, coding, reporting, and analysis of clinical and spontaneous adverse events—from multiple sources—in real-time. A global modular system that can be deployed as a client-server or Web-based solution, ARISg is 21 CFR 11 compliant, supports all E2B and MedDRA standards, and is also available as a Japanese, Kanji-based system. ARISg has a multitude of add-on options including: personalization Workflow with built-in Safety Alerts, in-depth Ad Hoc Analysis, Signal Risk Management with SafetyMART, and the ability to easily interface with other applications (e.g., CDMS, EDC, CTMS, Product Complaints, Drug Registration Tracking systems, etc.). You can also scan, store, and track documents, as well as link directly to Documentum.

**Assured Information Systems**

**PV-Works**

PV-Works is the leading workflow-driven pharmacovigilance system. It is 21 CFR 11 compliant, includes MedDRA coding and E2B. The software can inherit your own workflow processes and can be installed on site or run as an outsourced pharmacovigilance service. Assured and PV-Works are able to meet your pharmacovigilance system needs.

**Biomit, Inc.**

**Services**

Biomit, Inc. is an innovative clinical research organization (CRO) that combines the latest electronic data capture (EDC) technology with scientific expertise to ensure highly efficient service in conducting clinical trials. Our EDC software is an online tool that facilitates direct access to the trial data via your Internet browser. No need for local installation or validation of locally installed software on your computer system—yet another way that Biomit works to reduce the time and cost of your clinical trial!

**eResearch Technology, Inc.**

**eSafeNet**

An Internet-based adverse event management system. This application facilitates compliance by sponsors, clinical research organizations, and investigators with regulatory reporting requirements regarding adverse events and with the sponsor’s or clinical research organization’s own internal requirements for safety data analysis. Sponsors or clinical research organizations can configure this application to match their own processes and forms.

**iMedRIS**

**Clinical software**

At iMedRIS we provide state-of-the-art Electronic Research Administration software. Imagine an integrated research management system designed to reduce redundancy of data input while providing maximum data availability to all those who need it. Features include: IRB and site management, electronic submissions, configurable routing, EDC, ad hoc report writer, document differentiating, and a new application wizard.

**KIKI Medical**

**Eventa Suite**

See Clinical Project Management

**MAJARO InfoSystems Inc.**

**ClinAccess DictionaryCoder**

SAS-powered. Integrates with ClinAccess or as standalone. Works with any dictionary, including MedDRA, COSTART, WHO, or custom built. Autocodes exact matches. Flexible term search, learning capabilities, entered word as replacement, etc. to assist with encoded terms. Variety of reports. Used with entire system, images dynamically appear for easy coding.

**NetRegulus**

**NetRegulus v6**

NetRegulus v6 includes a comprehensive set of business process solutions that allow users to collect, analyze, report, share, and act on critical regulated data within one streamlined, 21 CFR Part 11 compliant package. The Adverse Event Tracking solution provides effective management for any event with patient or user implications. Use potent search-and-selection tools to quickly find adverse event issues and create new investigations. Attach digital records, assign tasks, generate form letters, run regulatory reports, and more.

**Oestreich & Partner GmbH**

**Adverse events**

Being an international full-service CRO founded 1991, we offer individual or generalized solutions for EDC-based trials and PMS projects using one of our own systems ORVERDI, PMS.BOX or any system of other vendors. ORVerdi has been used to document more than 25,000 cases in over 20 FDA/EMA relevant Phase I, II and III international clinical trials since 1998.

**PharmaNet**

**Services**

PharmaNet expertise is at the core of every eClinical Trial product from PharmaSoft, the Information Technology division of PharmaNet. PharmaSoft offers comprehensive product support services and a suite of Web-accessible products that facilitate the collection, management, and reporting of clinical trial information.

**Phase Forward**

**Clincare**

Phase Forward’s Clincare software is the industry’s premier safety reporting and tracking system. The software provides an adverse event tracking and reporting system that helps pharmaceutical companies monitor the safety of their products and comply with the reporting requirements of regulatory agencies worldwide. Clincare facilitates the collection, analysis, and reporting of adverse events, providing global access to critical safety information and a comprehensive company profile of product safety.

**Sierra Scientific Software, Inc.**

**Clinical Research Information System (CRIS), v7.1. See Trials Management and Administration**

**Winchester Business Systems, Inc.**

**adWATCH-e**

adWATCH helps the clinical trial team track AEs and SAEs as well as product inquiries and complaints from around the world. Integrates seamlessly with Protocol Manager, our clinical trials management system. Automatically generates CIOMS and MEDWAC 3500 reports for electronic submission. Uses MedDRA and/or user defined dictionaries. Conforms to 21 CFR 11.

**Clinical Project Management**

**BBK Healthcare, Inc.**

**TrialCentral**

TrialCentral is BBK's Internet-based application for clinical study patient enrollment data management. Not only does TrialCentral help to locate and process patient referrals, but it also provides a robust mechanism for compiling real-time information metrics. Thus, TrialCentral provides a platform for building a study community and improving communication among all parties—sponsors, investigators, investigative site staff, CROs, and other clinical study service providers.

**Biomit, Inc.**

**Services**

See Adverse Events

**ClinLogic**

**ClinTCMS**

ClinTCMS is a Clinical Trials Management System providing real-time insight into study progress. The system provides crucial information for decisions early in the study cycle before CRFs have been retrieved and entered into clinical data management. From site initiation through grant payment disbursement, ClinTCMS is an end-to-end solution.

**Clinical Source**

**TriaiX/TMS**

TriaiX/TMS is the integrated Web-based Trial Management System (CTMS) for your clinical research community, to plan, conduct, and effectively manage clinical trials through experience, collaboration, and consistent workflow. The TrialXIS Trial Management System (TMS) addresses the global management aspects of the entire clinical research process, including process planning, finance and resource management, monitoring tools, and much more.

**DatLab, Inc.**

**DatLabX**

DatLabX is an EDC software application built around a Microsoft platform, using its newest .NET servers, development tools, and framework. Because this is an extension of the popular Microsoft Office platform, it easily integrates with existing legacy systems. DatLabX integrates a full suite of clinical development products under the .NET umbrella, providing a seamless flow of information for clinical trial decision-making which will provide significant benefits, including an accelerated time to market, lower development costs and improved research quality.

**Datapharm Australia Pty. Ltd.**

**SMART**

SMART (Smooth Monitoring A Resource Tool) was developed by Datapharm to assist project managers of clinical trials to assess and track monitoring requirements over several projects and to adjust estimates based on actuals iteratively. It is quick to use and allows monitoring of actuals vs. estimated progress milestones.

**eResearch Technology, Inc.**

**Project Assurance**

A full spectrum of consulting and project assurance services that augment the implementation trial execution efforts of clients. The spectrum of services includes study initiation, project management, education, configuration, technology and regulatory review, research dashboards and electronic reporting, uniform standards and standard operating procedures, and migration services. The company provides on-site research and technology advisory services, support services, and a global customer care 24x7 help desk.

**etrials Worldwide, Inc.**

etrials provides a comprehensive eClinical solution that spans the entire clinical trial process for the healthcare, pharmaceutical and biotech industries. etrials’ QuickStudy suite of products offer first-class solutions to meet the industry’s data capture needs from lab data import and IVRS through online EDC and electronic patient diaries using handheld devices.

**Fortress Medical Systems, Inc.**

**Clindex**

Clindex provides a Clinical Trial Management System (CTMS), a Clinical Data Management System (CDMS), and Remote Data Entry (RDE/EDC) capability in one powerful, integrated software solution. The intuitive design of Clindex allows your client staff to design, implement, and manage studies efficiently and cost-effectively.

**ICTI Interactive Trial Management Solutions**

ICTI provides interactive trial management solutions using state-of-the-art IVRS development tools. Applications include centralized patient randomization, drug supply management, IVRS-based patient unblinding, patient diary data collection, accelerated patient referral, and automated information distribution. ICTI is the leader in clinical trial material management with the introduction of its powerful forecasting and supply chain management tool.

**iMedRIS**

**Clinical software**

See Adverse Events
Integic Corp.  
Clinical Trials Management System  See Trials Management and Administration

IntraLinks, Inc.  
IntraLinks  
IntraLinks enables companies to collaborate effectively outside the enterprise on complex business processes. Through IntraLinks’ trusted business hubs, companies are better able to compete globally by accelerating essential business processes, simplifying communication, and fostering rapid workflow. Our secure services enable instant and organized sharing of business-critical information among professionals, external partners and the advisors. IntraLinks is easily accessible anywhere, any time using a Web browser. Pharmaceutical companies use IntraLinks’ drug development hub to communicate and exchange information pertaining to clinical trials, drug licensing, mergers and acquisitions, and other complex, high-value business processes requiring collaboration with parties outside of the enterprise. IntraLinks services, which include a secure browser-based Internet application and 24/7/365 training, service and support, have been designed to comply with FDA and ICH computer system validation requirements.

KIKA Medical  
Event Suite  
KIKA Medical is a provider of 100% Web-based solutions dedicated to the management of clinical research studies, post-marketing studies, international registries, product surveillance programs, and complaints. Eventa Suite, KIKA Medical’s proprietary technology, is a secure, CTR Part 11 compliant, comprehensive solution for e-data collection, e-monitoring, e-data management, e-export, e-reporting, e-ACE management. Eventa Suite includes unique capabilities such as workflow management, centralization of digital imaging and ECG, and multilingual implementation (including Japanese).

MAJARO InfoSystems, Inc.  
ClinAccess CaseBook  See Document Management

Oestreich & Partner GmbH  
CRO Services  See Adverse Events

Outcome Sciences  
Outcome Project Management  
Outcome’s well tested Project Management methodology is designed to meet timelines and milestones. A carefully specified process, including a clear description of tasks and schedules, is reviewed with the sponsor at the onset. Combining EDC expertise and clinical study knowledge, Outcome project managers consistently perform all aspects of project administration, data coordination and tracking within time and budget goals.

Perceptive Informatics, Inc.  
IMPACT  See Trials Management and Administration

PharmaNet  
Services  See Adverse Events

ProIRB Plus, Inc.  
ProIRB  
ProIRB is a multi-user, multi-IRB software application providing productivity and compliance assurance tools for managing the institutional review board work-flow process from scheduling to meeting minutes. The application is developed in MS Access and is currently in use by major universities and healthcare institutions nationwide.

Propack Data  
PMX CTM Solution  
As a result of long-time experience and close cooperation with leading life sciences companies, PMX CTM represents a software suite tailored for the specific demands of pharmaceutical development, clinical manufacturing, and clinical trial management. Our PMX CTM solution is based on the release-controlled PMX applications well-established in the pharmaceutical and biotechnology industries. It meets the requirements of the highly sensitive and regulated market of clinical studies and complies with cGMP/GCP guidelines. The process oriented solution focuses on both efficiency of the application and the safety demands of regulatory authorities.

Scientific Software Tools, Inc.  
VISTA  
VISTA, the remote technology assessment tool, is used to verify existing hardware, software and Internet connectivity at remote investigative sites prior to study initiation. This tool can drastically increase the speed of site assessment over traditional methods and greatly reduces costs associated with assessment, remediation, lost investiga- tors, and poor user experience. SST also develops custom EDC applications for PDAs, clinical portals, and PHR complaint market awareness software.

TrialTrac, Inc.  
SiteTrac  See Trials Management and Administration

Winchester Business Systems, Inc.  
Custom application development  
Winchester Business Systems develops software applications for pharmaceutical, biotechnology, and medical device companies designed to improve drug and product development processes. Winchester implements systems for multisite/multivendor clinical trials projects, electronic data collection, workflow management and project management systems, information management, and exception reporting for decision support.

Custom Application Development

BioPharm Systems, Inc.  
Clinical IT Systems Custom Development  
BioPharm Systems provides critical implementation and integration services in the areas of clinical data management, safety reporting, electronic data capture, dictionary management, and clinical trial management. Our architects and developers can assist you with developing a custom solution or an enhancement to a vendor system based on your company’s individual needs.

CiteLine, Inc.  
Custom application development  
CiteLine, Inc. is an information services and application development company serving the Pharmaceutical and Biotechnology industries. Our currently offer a line of Web research products and consulting services that provide organized access to the best medical industry information available on the Internet, including ongoing clinical trials information. Additionally, we offer customized application development services and have implemented solutions for Top 10 pharmaceutical companies globally.

ClinLogic Services  
ClinLogic is a Microsoft Certified Partner able to provide custom software development for clinical trial solutions. We have experience developing mission-critical systems for pharmaceutical companies, large sites, CROs, and patient recruiting firms. In addition, ClinLogic provides custom Web design for company Web sites or intranet sites. Our combination of clinical trials domain expertise and technical skills makes ClinLogic the best choice for your custom software development needs.

Formedix, Inc.  
Custom application development  
Examples include: development of bespoke EDC systems, customization of existing Formedix products to exact client requirements, conversion from existing data standards formats and metadata, building of CDISC exporters, XML development, custom report engines and output formats from proprietary EDC/CDMS systems.

GEREQ  
Custom application developments  
GEREQ, an Application Service Provider (ASP), offers many services, including the following: online randomization, and treatment supply management, remote data entry (with online controls and validation, Web-based query generation and management, and electronic signatures), automatic and assisted coding, Data Clarification Form (DCF) including audit trials, real-time progress reports, event-triggered notifications, monitoring management (in development), site quality reports, trial-specific Web site, remote database set-up, study subject data entry design application, training services for users, compliant 21 CFR 11, and compliant CDISC.

Hyphen INSPIRE  
In addition to the INSPIRE EDC system, Hyphen has created a mobile detailing device (eRENALENIE) for pharmaceutical medical and sales professionals. Hyphen also creates custom applications, such as customized Web-based training, corporate, product, and study Web site, registry portals, CD-ROMs, and other unique interactive applications for clinical and marketing areas.

iMedRIS  
Clinical software  See Adverse Events

Insightful  
S+SeqTrial  
S+SeqTrial is an S-PHUS software library for designing, monitoring, and analyzing clinical trials using group sequential methods. The main design focus is choosing the sample size that allows the clinical trial to discriminate between the null and alternative hypotheses, thereby answering the scientific questions of interest.

Integic Corp.  
Custom Development  
Custom development engagements can allow clients to extend the capabilities of Integic applications or legacy applications, as well as offer ground-up implementation of new design.

Keris, Inc.  
Multimedia Informed Consent Sessions  See Knowledge Management

Oestreich & Partner GmbH  
CRO Services  See Adverse Events

PharmaNet  
Services  See Adverse Events

Scientific Software Tools, Inc.  
VISTA  See Clinical Project Management

StudyBuilder Limited  
StudyBuilder Design Consultancy  See IT Consulting

Target Health, Inc.  
Target e-CRF  See Electronic Data Capture

Waife & Associates, Inc.  
Process Change  
Waife & Associates, Inc. is a change management consulting firm which focuses on planning for and implementing process change, including IT adoption, in clinical research. Areas of expertise include EDC, CDMS, AES, CTMS, and EPDs.

Data Collection and Management

Aris Global  
ARISg  See Adverse Events

Aris Global  
ClinTALK  See Wireless and Mobile Technology

Biomit, Inc.  
Services  See Adverse Events

BioPharm Systems, Inc.  
OCscan  BioPharm Systems’ OCscan product integrates with Oracle Clinical for automatic faxing and scanning of CRFs and DCFs. OCscan replaces front-end data entry in Oracle Clinical with high-speed data entry in TELEform and then automatically populates data in Oracle Clinical. Electronic images of forms are available for access from Oracle Clinical, and for electronic submissions to the FDA.
Cardio Control

ABP Perfect
PC-based Ambulatory Blood Pressure system. Includes management of data. Optional software for data transmission and management.

Clinical DataFax Systems, Inc.
DataFax
A complete clinical trials management solution using CRFs and simple fax technology at the clinical sites and powerful software at the coordinating center including: intelligent character recognition from faxed CRFs, query tracking, standard reports, audit trails, study setup tool, bookmarked PDFs of patient CRFs, acceptance test kit, and much more.

ClinicalTrialsNet, Inc.
ClinNet
ClinicalTrialsNet has developed a Web-based system that enables comprehensive data, project, and document management in a regulatory compliant, on-line environment. Our intuitive user interface makes it easier for you to focus on trial management, instead of trial software management. Contact us to bring efficient technology to your trials!

ClinLogic

Services
ClinLogic provides custom database design and validation for clinical trials. We provide Microsoft SQL Server solutions and personal services to meet your data management needs.

ClinPhone

Data collection
Today ClinPhone’s range of services are driven by a unique integration of Internet and telephone based technologies enabling process improvement for pharmaceutical and biotech sponsors as well as CRO partners. The tangible benefits include: Internet-based and IVR centralization, Real-time project tracking and study management information, Reduced storage and wastage of trial supplies, Improved quality and efficiency in collecting secure, accurate data throughout Phases II, III and IV of the clinical trial process. Additionally all technology solutions and tailored study services are fully validated and 21 CFR Part 11 compliant.

ClinSource

TriaxXS/CRF
See Electronic Data Capture

TriaxXS/PDE
TriaxXS/PDE offers flexible possibilities to filter the output based on countries, sites, patients, or data status. TriaxXS/PDE guarantees highly secured and encrypted data transfer.

DataSpectrum, Inc.
Data & Statistical Services
DataSpectrum is an innovative data and statistical services company, providing the ability to use EDC, paper, and fax data collection methods in one study, in one validated system, using Oracle Clinical, giving you the flexibility to pick a site based on patient enrollment and quality—not the site’s technological ability.

eResearch Technology, Inc.
eData Management
An Internet-based technology for collecting, editing, and managing clinical trial data in any computing environment. Customers use this technology to analyze data, resolve incomplete or erroneous data entries, and support early locking of the database for a particular trial. This product easily integrates with a wide variety of third-party applications for imaging, workflow, and data analysis.

eResearch Technology, Inc.
EXPRT
Intelligent, workflow-enabled data handling and distribution of paper-based and digital ECG data and images as well as analysis and cardiologist interpretation of ECGs performed on research subjects in connection with the Company’s customers’ clinical trials. This service permits assessment of the safety of therapies by documenting the occurrence of cardiac electrical charge.

eTrials Worldwide, Inc.
See Clinical Project Management

Formedix, Inc.
Formedix Origin
Formedix Origin: A unique family of trial authoring and specification tools utilizing CDISC standards to markedly reduce study set up time. Origin Study Modeler is the first commercially available tool allowing study designers to capture the content and structure (metadata) of their clinical databases in a format adhering to the emerging pharmaceutical industry data standard, the Operational Data Model (ODM), created by CDISC.

Fortress Medical Systems, Inc.
ClinDex
See Clinical Project Management

GHERE
See Custom Application Development

Gupta Programming
Best Practices Clinical Trial Reporting Templates
Expedite and standardize new development based on pre-built and validated best practices clinical trial reporting templates. Reuse and customize best practices templates to individual clinical trial studies. Ideal environment for leveraging and reusing existing SAS code. Ensure compliance by using best practices SOP and validation documentation for IQ and OQ requirements.

Hyphen
INSPIRE See Custom Application Development

iMedRIS
Clinical software See Adverse Events

InfMed Limited
MACHO See Electronic Data Capture

Integic Corp.
CRF WorkManager
CRF WorkManager combines award-winning workflow and trials automation technology to provide speed, flexibility, and control to standardize and accelerate global clinical trial processing. By employing multiple technologies for a total solution, CRF WorkManager reduces the time and cost required to manage documents during clinical trials and allows document processing and access across multiple geographic regions. Features include remote data capture by fax or scan, integration with leading clinical databases around split screen data entry, discrepancy processing, and study setup, automated indexing through barcode and optical recognition technology, tracking of productivity metrics, patient tracking, DCF/query processing, and automated email notifications.

Integic Corp.
Clinical Trials Management System
See Trials Management and Administration

invivodata, Inc.
invivosystem
invivodata's electronic patient diary system combines behavioral and clinical science with handheld and Web technology to deliver real-time patient self-report data in clinical trials. invivodata's science-based diary methods and proven technology optimize patient compliance and study sensitivity to maximize confidence in trial data.

Keris, Inc.
Vital Source
The Vital Source clinical data management system (CDMS) is a flexible and secure data repository. Its intuitive format ensures that any user, regardless of computer skill level, can set up an effective study database, collect and export data into a statistical analysis tool, and quickly generate study reports.

KIKA Medical
Events Suite See Clinical Project Management

Logos Technologies Ltd.
ALPHADAS See Electronic Data Capture

MAJARO InfoSystems, Inc.
ClinAccess PowerServer
Validated SAS-powered clinical data management software with integrated dictionary autoencoder, data clarification system, workflow, imaging, and Web components. Study setup wizards, automated forms tracking, CRF images received from scan, fax, or file links directly to data for view throughout system. Completely operational within 30 days. Easily customizable by client.

MAJARO InfoSystems, Inc.
ClinAccess Web See Web-Based Software Services

Mini Mitter Co., Inc.
Actiwatch Actigraphy Monitors See Electronic Data Capture

NetRegulus
NetRegulus 6® See Electronic Data Capture

Oestreich & Partner GmbH
CR0 Services See Adverse Events

Outcome Sciences
Outcome 7.0 See Electronic Data Capture

Perceptive Informatics, Inc.
INITIATOR
INITIATOR is a complete solution for improving productivity and access to both operational and planning data in the Phase I arena. Using electronic data capture techniques, INITIATOR provides fast access to real-time, quality assured data. And the system automates many labor-intensive tasks to ensure that studies are conducted cost effectively.

Perceptive Informatics, Inc.
Perceptive Voice
Perceptive Voice is an industryleading product able to enroll patients, effect complex randomizations, offer “just-in-time” inventory management, handle drug dosing and collect patient diary information.

Perceptive Informatics, Inc.
Perceptive Portal
Perceptive Portal provides a secure way to proactively manage individual trials or an entire development portfolio by presenting key information to key stakeholders. A collection of Web tools (for example, reports, metrics analysis, document repository, IMPACT access) provide a comprehensive view of progress on clinical trials.

Perceptive Informatics, Inc.
Perceptive Imaging
Perceptive Imaging offers a service which meets the needs of: trials consulting, image collection, image analysis and review, and regulatory submission. In particular, our service uses the latest technology and covers a wide range of therapeutic areas. Specifically, Perceptive is successfully using MR, CT and PET scans, x-ray, DAX, ultrasound and digital photography, and other advanced imaging modalities as surrogate end points.

PerMedics, Inc.
Surveyor EDC System
Surveyor enables data managers to obtain trial data in real time from anywhere in the world. Complex case report forms with validation and edit checks are designed easily using design templates. The XML based system is 21 CFR 11 compliant with audit trail and multi-level security features. PerMedics’ software suite includes trial management solutions.

PerMedics, Inc.
Services See Adverse Events

PharmaNet
See Electronic Data Capture

PIER Ecoinformatics
PIER Ecoinformatics is an online data management system for environmental regulatory and private sector applications. PIER supports clinical and non-clinical data entry, analysis, and management in a single, easy-to-use interface.

PharmaNet
See Clinical Project Management
PharmaPros Corporation  
DataVal See Other Applications

PharmaPros Corporation  
NCompass  
NCompass is a comprehensive clinical systems environment that provides Clintrial, Clintrace, CRFTrack, DataVal and other third-party products as an integrated Web-based solution. NCompass includes all the software, services, and technical support needed to run clinical trials.

Pharsight Corp.  
Pharsight Knowledgebase Server See Knowledge Management

Phase Forward  
Clintrial  
Phase Forward’s Clintrial system is the market-leading clinical data management system. Thousands of trials are currently managed in Clintrial. Through simplifying the management of clinical data, this time-tested system increases organizational productivity, enhances data quality, and promotes standardized clinical research operations. No other CDMS system is as fast to get up and running. No other CDMS application offers as intuitive an interface — reducing the dependence on Oracle experts.

Phoenix Data Systems  
IT Applications  
Phoenix Data Systems (PDS) is a mature data services company offering a variety of sophisticated software products and service offerings for electronic data capture, clinical study management, and data management. PDS EDC products have served as the electronic data collection platforms for pivotal trials for several regulatory submissions approved by FDA and other regulatory authorities.

PHT Corp.  
ePRO Solutions  
PHT is the leading global provider of ePRO solutions. Our products include the LogPad e-diary, Wireless LogPad, LogPad Phone — our mobile phone based e-diary, PHT’s StudyPad for data collection at sites, and the Web-based StudyWorks for data collection, review and management. We also offer the most comprehensive collection of study support, technology transfer and client services available in the industry. Our experience includes more than 80 clinical trials with over 45,000 patients.

QualityMetric, Inc.  
SF Health Surveys  
Founded in 1997 by John E. Ware, Jr., PhD, principal developer of the SF-36, SF-36v2, SF-12, SF12v2, and SF-8 Health Surveys, QualityMetric, Inc. has integrated the consumer’s voice into health care decision-making with self-reported health outcomes surveys used worldwide to measure health status with scientific validity in clinical practice, disease management, population monitoring, risk assessment, clinical trials, and direct-to-consumer marketing. Building on this milestone, QualityMetric developed the SF Health Outcomes Scoring Software, a desktop scoring application to assist SF survey users in determining the quality of data, estimate scores for missing data, and achieve forward and backward comparability of scores for any of the SF Generic Health Surveys.

Scientific Software Tools, Inc.  
VISTA See Clinical Project Management

SigmaSoft International  
DMSys  
A powerful, easy to use and affordable data management system for clinical trials, DMSys provides a complete package to perform data management from study setup to exporting clean data for statistical analysis. A 21 CFR 11 compliant package designed for small to medium CROs and companies. Complete with query management, data cleaning tools, data and user access security, and many practical data management features to improve your efficiency and cost effectiveness.

StudyBuilder Limited  
Complete Introduction to StudyBuilder Training Course  
See Training

SyMetric Sciences, Inc.  
SyMetric Clinical Data Management System  
Comprehensive data management system for clinical trials including full support for double data entry, multivariate data validation, data dictionary, autoencoders for all standard dictionaries (ICD9, MedDRA, WHO, etc.), query management, flexible export to ASCII, HTML, and SAS, etc. Complies with all regulatory requirements.

Synapse  
RegTracker see Knowledge Management

Synteract  
SynCoder  
SynCoder is an SAS application that implements the MedDRA terminology, as well as COSTART and WHO-DRUG dictionaries, for coding adverse event and medication text reported during clinical trials or post-marketing. The product requires SAS v8.1 or higher, and works with SAS v6 or v8 databases.

Vitalograph Ltd.  
Spirotrac Centralized Spirometry System See Electronic Data Capture

Waife & Associates, Inc.  
Process Change See Custom Application Development
Data Mining and Visualization

Biomit, Inc.
Services See Adverse Events

CiteLine, Inc.
Mining See Custom Application Development

ClinSource
TriaxS/PDE See Data Collection and Management

iMedRIS
Clinical software See Adverse Events

Insightful
Insightful Miner Desktop Edition is the first affordable, no-compromise data mining workbench that gives new data miners and skilled modelers the ability to deploy predictive intelligence throughout the enterprise.

PharmaNet
Services See Adverse Events

NetRegulus
NetRegulus v6
NetRegulus v6 includes a sophisticated reporting utility to provide detailed, Web-based analytical reporting for decision makers, as well as regulatory reporting for all phases of a product’s life cycle. Includes a library of standard reports and simple point-and-click tools to create unlimited ad hoc reports, charts, and graphs. Generates and automatically emails regularly scheduled reports.

Electronic Data Capture

Acumen Healthcare Solutions, LLC
Tract12k EDC System
Tract12k is the most affordable and flexible EDC solution available today. Quickly and easily create, design, and modify your own e-CRF’s complete with error checks and comprehensive audit trails. If you need a system to accommodate offline and/or on-line data entry without changing your database, Tract12k can do it affordably.

Biomit, Inc.
Services See Adverse Events

Cardio Control
Recollect
ECG event recorder system for acquisition of high-resolution ECG data. System can record up to 180 minutes of data, 1 or 2 channels.

Clinical DataFax Systems, Inc.
DataFax
See Data Collection and Management

Clintrac
Clintrac Patient Diary, Clintrac Visit Diary
Wireless patient diary that enables collection and monitoring of patient data in real-time.

Clinphone
Data collection See Data Collection and Management

ClinSource
TriaxS/CRF
TriaxS/CRF is a Web-enabled CRF design tool to create, design, program, and change Clinical Research Forms in a fast, accurate, remote, and secure environment. It works fully integrated with the TrialXS trial management and data capture systems.

DataLabs, Inc.
DataLabsXC See Clinical Project Management

Datapharm Australia Pty. Ltd.
e-CRF
e-CRF is a remote data capture tool allowing sites to enter clinical data offline at the site and send clinical trial data electronically to Datapharm’s secure server. Fields are programmed with edit checks and database lookups allowing quick access to clean data which can be viewed on the Web. System setup and maintenance is cost effective.

DataSpectrum, Inc.
Data & Statistical Services See Data Collection and Management

DATATRAK Deutschland GmbH/ DATATRAK International, Inc.
DATATRAK EDC
DATATRAK International, Inc., with offices in Cleveland, OH, and Bonn, Germany, specializes in electronic data capture using DATATRAK EDC. The product suite operates in centralized or stand-alone modes, and offers state-of-the-art security and real-time data entry and review. Electronic site assessment, Web-based training offered.

Dynarand
Electronic Diaries
Dynarand’s Interactive Voice Response (IVR) and Web-based Electronic Diaries are a convenient, user-friendly means of collecting patient data and improving patient compliance. They provide an economic alternative to other diary collection methods.

eResearch Technology, Inc.
eData Entry
An electronic data capture (EDC) system permitting investigators to use standard Internet browser tools to input data into a centralized database in an online or offline environment. eData Entry accommodates traditional manual, paper-based data entry, data entry using the Internet and other forms of electronic data transmission. eData Entry can also capture data in the form of electronic images.

etrials Worldwide, Inc.
See Clinical Project Management

Formedix, Inc.
Formedix Express
Two innovative EDC solutions which can be delivered online, offline, distributed, mobile and wirelessly, and are applicable in any clinical environment. Unique Phase I solutions facilitate real time concurrent data entry enabling rapid throughput of subjects. EDC systems can be built rapidly and all the data can be exported to the vendor-neutral Operational Data Model (ODM) format.

Fortress Medical Systems, Inc.
Data & Statistical Services

GEREQ
See Clinical Project Management

InferMed Limited
MACRO
MACRO is InferMed’s electronic data capture solution for clinical trials. MACRO is an easy-to-use system that can guide you smoothly through the transition from paper to electronic clinical data capture systems. MACRO has intuitive, interactive tools for study definition, on-line and offline remote data entry and study monitoring. MACRO is the only independent EDC system fully integrated with Oracle Clinical.

Document Management

Aris Global
REGISTER See Knowledge Management

Biomit, Inc.
Services See Adverse Events

iMedRIS
Clinical software See Adverse Events

Integic Corp.
CRF WorkManager
See Data Collection and Management

IntraLinks, Inc.
IntraLinks See Clinical Project Management

MAJARO InfoSystems, Inc.
ClinAccess CaseBook
An imaging component, designed to take advantage of full integration with our PowerServer product. Receives images from fax, scan, or file format making this “case book oriented” imaging system very flexible. Recently we added OCR (optical character recognition) capabilities for use in situations where appropriate. Integration with PowerServer not only eliminates duplicity of efforts and simplifies validation, it keeps the image tied to the data at all times. Combined with a group of management tools for annotating forms, multiple view, and search tools, workflow capabilities make this component revolutionary in clinical data management.

PharmaNet
Services See Adverse Events

Pharsight Corp.
Pharsight Knowledgebase Server See Knowledge Management

Scientific Software Tools, Inc.
VISTA See Clinical Project Management

Synapse
RegTracker See Knowledge Management

Winchester Business Systems, Inc.
Health Agency Tracking
The Health Agency Tracking system tracks all documents associated with queries and responses made by and to regulatory agencies. Automatic workflow notifies all interested parties and initiates action items for resolution of the query. Maintains complete audit trail. Conforms to 21 CFR 11 regulations for electronic records and signatures.

Data Warehousing

GEREQ
See Custom Application Development

Hyphen
INSPIRE See Custom Application Development

iMedRIS
Clinical software See Adverse Events

Keris, Inc.
Vital Source See Data Collection and Management

Oestreich & Partner GmbH
CRO Services See Adverse Events

PharmaNet
Services See Adverse Events

Pharsight Corp.
Pharsight Knowledgebase Server See Knowledge Management

Electronic Images

IntraLinks
See Classic Project Management

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Acumen Healthcare Solutions, LLC
Tract12k EDC System
Tract12k is the most affordable and flexible EDC solution available today. Quickly and easily create, design, and modify your own e-CRF’s complete with error checks and comprehensive audit trails. If you need a system to accommodate offline and/or on-line data entry without changing your database, Tract12k can do it affordably.

Biomit, Inc.
Services See Adverse Events

Cardio Control
Recollect
ECG event recorder system for acquisition of high-resolution ECG data. System can record up to 180 minutes of data, 1 or 2 channels.

Clinical DataFax Systems, Inc.
DataFax
See Data Collection and Management

Clintrac
Clintrac Patient Diary, Clintrac Visit Diary
Wireless patient diary that enables collection and monitoring of patient data in real-time.

Clinphone
Data collection See Data Collection and Management

ClinSource
TriaxS/CRF
TriaxS/CRF is a Web-enabled CRF design tool to create, design, program, and change Clinical Research Forms in a fast, accurate, remote, and secure environment. It works fully integrated with the TrialXS trial management and data capture systems.

DataLabs, Inc.
DataLabsXC See Clinical Project Management

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Our applications include electronic CRFs, patient enrollment tracking, randomization, validation, data capture, and data exports (with audit trail) on demand. TrialMaster Archive and Ph. I also available.

**Outcome Sciences**

**Outcome 7.0**
The proven scalability and reliability of Outcome's Web-based data collection and management system offers sponsors unprecedented flexibility for their post-marketing studies. The robust reporting system allows sponsors to evaluate data and base decisions on real-time information. The value added features of the system makes it extremely easy for sites to integrate into their workflow, increasing productivity and effectiveness.

**PerMedics, Inc.**

Surveyor EDC System See Data Collection and Management

**PharmaNet Services** See Adverse Events

**Phase Forward**

**InForm**
Phase Forward's InForm software uses Internet technologies to conduct and manage clinical trials efficiently and effectively. The InForm system leverages an intuitive interface and clinical trial environment to increase the productivity of study coordinators, monitors, clinical data managers, and project managers. The InForm software includes a powerful eCRF authoring environment unmatched by competitors. The InForm system scales to handle high volume, global trials.

**Phoenix Data Systems**

**IT Applications** See Data Collection and Management

**PHT Corp.**

ePRO Solutions See Data Collection and Management

**Scientific Software Tools, Inc.**

**VISTA** See Clinical Project Management

**StudyBuilder Limited**

**StudyBuilder Enterprise Edition**
StudyBuilder Enterprise Edition ($4999/study designer; no site/subject/data manager fees) integrated study design, data management, and collection software package. Use wizards and drag-and-drop to design and deploy your study. Includes data collection and management system for Web, palmtop, and desktop computers and integrates data from spirometers, etc. automatically.

**Target Health, Inc.**

**Target e+CRF**
Target e+CRF is a propriety Internet-based remote data entry, data management, and project management system, created and managed exclusively by Target Health Inc. Data are entered through a Web interface (browser) directly to a remote database. No software is installed and the system is fully functional even if used with a 28.8 modem. The system is validated and 21 CFR 11 compliant. An NDA was recently approved which used the system. The FDA site audit was flawless.

**Vitalograph Inc**

**Electronic PEF/FEV1 Diary system**
As above for data transfer or via mobile phone direct from the clinic software can be interfaced with an Internet EDC system, created and managed exclusively by Target Health Inc. Data are entered through a Web interface (browser) directly to a remote database. No software is installed and the system is fully functional even if used with a 28.8 modem. The system is validated and 21 CFR 11 compliant. An NDA was recently approved which used the system. The FDA site audit was flawless.

**VITALlograph Ltd.**

**Spirotac Centralized Spirometry System**
Vitalograph has been a world leader in respiratory diagnostics for almost 40 years. The Centralized Spirometry System transmits encrypted data everyday via email from investigator sites directly to the sponsor or via a dedicated and unique over-read software system where data quality is ensured on a daily basis. Alternatively, the clinic software can be interfaced with an Internet EDC system for data exchange.

**Waife & Associates, Inc.**

**Process Change** See Custom Application Development
Datafarm, Inc. Clinical Information Technology Consulting See Electronic Submissions

eResearch Technology, Inc. Project Assurance See Clinical Project Management

First Consulting Group Services
First Consulting Group is a leading provider of information-based consulting, integration, and IT outsourcing services for healthcare, pharmaceutical and other life sciences organizations in North America, Europe, and Asia. The firm’s services are designed to increase its clients’ operational effectiveness, resulting in reduced costs, improved customer service, enhanced quality of patient care, and the more rapid introduction of new pharmaceutical compounds. Using our extensive industry and technical expertise, FCG provides content management solutions tailored to satisfy the business needs of our clients. FCG has led over 140 successful implementations for more than 50 companies. Using best practices and industry leading technology, FCG has developed the FirstDoc product suite.

Formedix, Inc. Connect
A comprehensive range of consultancy, training, and implementation services incorporating the client’s expertise, and knowledge we have acquired while developing and deploying innovative standards-based products and services. Our experts have over 15 years of data standards experience. Formedix is a CDISC Registered Solution Provider and is ideally placed to assist you in facilitating standards adoption within your clinical development life cycle.

iMedRIS Clinical software See Adverse Events

InfoPro Solutions Clinica Suite See Trials Management and Administration

Insightful S+SeqTrial See Custom Application Development

Integic Corp. Strategic Consulting
Integic leverages years of life sciences experience and knowledge to offer an array of high-value strategic consulting services on such topics as work process improvement, IT strategy, and enterprise applications.

Oestreich & Partner GmbH CRO Services See Adverse Events

PharmaNet Services See Adverse Events

Phase Forward Consulting
In supporting a diverse set of customers, each having unique needs and business objectives, Phase Forward offers a flexible services portfolio through which the benefits of technology-powered trials can be realized. The Company’s InPhase/SM offering is a comprehensive platform that provides opportunities to leverage Phase Forward’s extensive experience and expertise to design and implement solutions that help our customers meet their goals. InPhase/SM is designed to support the entire clinical development process, from planning to execution and reporting. It provides a flexible, scalable, and comprehensive solution to meet the needs of modern clinical trials.”

StudyBuilder Limited StudyBuilder Design Consultancy
StudyBuilder Consulting (from $99 per hour on-site, $299 per hour off-site). Outsource study design and implementation based on StudyBuilder products to our consultants including protocol and paper case report format design (including layout, development of validation criteria, documentation, and testing). Typical project requires between 40 and 160 hours of consultancy.

Waife & Associates, Inc. Process Change See Custom Application Development

Knowledge Management

Aris Global REGISTER
The most comprehensive global drug registration and tracking system. Compliant with the latest regulatory guidelines, REGISTER provides for reliable and accurate product information (e.g., preferred name, ingredients, international birth date, registration renewal, approval status, registration number, etc.), global monitoring of activities, and compliance for manufacturing and QC regulations.

Biomit, Inc. Services See Adverse Events

CiteLine Inc. Management See Custom Application Development

eResearch Technology, Inc. eResearch Community
A central command and control portal that provides real-time information related to monitoring clinical trial activities, data collection, and safety. This Internet-based tool, which includes research dashboard and health education modules, allows participants in the clinical trial to follow the progress and conduct of a study based on frequently updated data using the Internet. The participant can analyze data and generate reports in a broad variety of formats that permit early strategic intervention in the clinical trial.

Insightful InFact
InFact is currently the only commercial technology of its kind to embody humanlike intelligence, thereby empowering knowledge workers and decision-makers to make better decisions faster in a wide range of critical, high-value business areas.

Keris, Inc. Multimedia Informed Consent Sessions
Multimedia consent sessions improve adherence to clinical trial protocols and significantly increase patient retention within the trial. These sessions use 3D animations, text, and exam questions to educate subjects and verify their understanding. Multilingual presentation and content written at a 6-8th grade level guarantees subjects can easily understand the information.


NetRegulus
NetRegulus v6 includes a comprehensive set of business process solutions that allow users to collect, analyze, report, share, and act on critical regulated data within one streamlined, 21 CFR Part 11 compliant package. Representative solutions include Study Data Management, Adverse Event Tracking, CAPA Management, Complaint Handling, Nonconformance Management, and others, to provide organizations with a flexible, enterprise approach to clinical, quality, and regulatory data management.

PharmaNet Services See Adverse Events

Pharsight Corp. Pharsight Knowledgebase Server
The Pharsight Knowledgebase Server (PKS) provides a unified repository for modeling and analysis activities, including the capture and maintenance of computed model parameters and other derived information, across a large set of compounds and development phases. The PKS suite provides productivity tools, integration with common data management systems and desktop environments such as Oracle Clinical and Microsoft Office, and a platform for automating and standardizing common tasks such as data transformations/loading and authoring of reports for regulatory submissions.

SAS Institute, Inc. SAS Drug Development
By streamlining research activities, providing centralized Web-based data access, automating processes for complying with government regulations and industry standards, and offering core data transformation, analysis, and reporting tools, SAS Drug Development provides the intelligence needed to make more informed clinical and business decisions, ultimately bringing drugs to market more quickly and efficiently.

Synapse RegTracker
The straightforward project and data management tool that streamlines your registration and licensing processes worldwide. Putting critical product information at your fingertips, regardless of geographic location, employees in regulatory affairs, marketing, safety, and quality assurance can collect, search, share, and report vital product registration information quickly and effectively. The system is Web-enabled and compliant with the latest standards and regulations.

Statistical Analysis


Biomit, Inc. Services See Adverse Events

Cytel Software Corp. East
East software is the industry standard for design, simulation and interim monitoring of group sequential and adaptive clinical trials. Cytel also offers expertly designed, flexible clinical trials to help you find the correct answer sooner. Choose Cytel, thought leaders in advanced biostatistics, for fast track protocol development, adaptive clinical trials and regulatory guidance.

DataSpectrum, Inc. Data & Statistical Services See Data Collection and Management

Gupta Programming Best Practices Clinical Trial Reporting Templates See Data Collection and Management

idv Data Analysis & Study Planning
Program for planning and interpreting sample size and related topics within the framework of the Wilcoxon-Mann-Whitney test. Target parameters include sample size, alpha, beta, and the smallest detectable difference expressed as Mann-Whitney statistic. It supports tests for difference and tests for equivalence/non-inferiority, one-sided and two-sided. System(s): DOS, Windows 98/2000/NT/XP/ME.

Insightful S-PLUS
SPLUS is the premier solution for exploratory data analysis and statistical modeling. With over 4,200 data analysis functions, including the most comprehensive set of robust and modern methods available anywhere, SPLUS allows you to perform more insightful analysis, create revealing graphics and make more informed business decisions.


February 2004
Oestreich & Partner GmbH
CRO Services See Adverse Events
PharmaNet
Services See Adverse Events
Pharsight Corp.
Pharsight Knowledgebase Server See Knowledge Management
QualityMetric, Inc.
SF Health Surveys See Data Collection and Management

Training

Biomit, Inc.
Services See Adverse Events
BioPharm Systems, Inc.
Training Courses
BioPharm Systems offers public and on-site training courses for Oracle Clinical, TMS, and AERS. Each course includes lectures, demonstrations and hands-on exercises. Students are provided with access to live Oracle Clinical, TMS, and AERS databases. We also offer a 21 CFR Part 11 requirements training course.

ePharmaLearning
eMeetings, eLearning See Web-Based Software
Formedix, Inc.
Connect
A full range of training services customized to client requirements. Specialist subjects include conversion of data from legacy systems and interpretation and implementation of clinical data standards, in particular those of the Clinical Data Interchange Standards Consortium (CDISC).

GEREQ
See Custom Application Development
Hyphen
INSPIRE See Custom Application Development
iMedRIS
Clinical software See Adverse Events
Insightful Training See Custom Application Development
PharmaNet
Services See Adverse Events
StudyBuilder Limited
Complete Introduction to StudyBuilder Training Course
Complete Introduction to StudyBuilder Training Course ($499/CD-ROM, DVD, video). An interactive multimedia guide to using StudyBuilder tools for study design, data collection and management.

Validation Wizards International
Validation Wizard for Application User Teams
Validation Wizard for Application User Teams is a “read and click” application that trains the trainer and the user team in the ABCs of computerized system validation (CSV) for user acceptance of regulated systems. Wizard teaches a common-sense approach for integrating CSV into the normal workflow of regulated areas.

Trials Management and Administration

Aris Global
globalTRIALS
A comprehensive Web-based clinical trials project management system (CTMS) for the collection, management, sharing, analysis, and reporting of study performance data. With remote data entry support via a standard Web browser, globalTRIALS enhances study set-up, project management, studyometrics, and tracking, study subject enrollment, supplies tracking, adverse event tracking, electronic document exchange, and tracking, etc.

Aris Global
inforMED
inforMED is Aris Global’s medical information communications system, for reporting medical inquiries.

Biomit, Inc.
Services See Adverse Events
ClinLogic
ClinCTMS See Clinical Project Management
ClinLogic
ClinSite
ClinSite is a comprehensive solution for SMOs and research sites, managing all aspects of clinical trial participation from prospecting and enrollment to grant payments and patient stipends. The system tracks visits and procedures and can enforce protocol visit windows. ClinSite also includes call center management, media effectiveness, and medical records.

ClinSource
TrialXS/TMS See Clinical Project Management

Convergence CT
HARP
Convergence CT has developed a set of software tools designed to help health care institutions engaged in research comply with HIPAA’s privacy rule and manage the administrative burdens associated with HIPAA compliance. Convergence CT’s integrated software and workflow system, HARP (HIPAA Automation for Research Programs), is designed to facilitate use of valuable health information for research, thereby improving research productivity, while providing covered entities with a secure HIPAA compliant system.

Datapharm Australia Pty. Ltd.
SMART See Clinical Project Management

Data Spectrum, Inc.
Data & Statistical Services See Data Collection and Management

eResearch Technology, Inc.
eStudy Conduct
An Internet-based technology to set up clinical trials, establish standards, track study activities, plan resources, distribute supplies, manage the financial aspects of a trial, and electronically view clinical trial data on the Internet.

Fortress Medical Systems, Inc.
ClinEdge See Clinical Project Management

Honeywell/POMS
POMS CMS
Manufacturing execution systems for clinical supplies manufacturing.

ivdata Data Analysis & Study Planning
Rancode Plus 3.6
Program for randomizing trial subjects according to the permuted block scheme with constant or varying block size. It prepares random code lists, sealed envelopes, and stick-on labels. Rancode Professional comes with many facilities for working in a validated environment according to GDP and FDA regulations. Partial decoding possible according to a predefined subject list. System(s): DOS/Windows 98/2000/NT/XP/ME.

iMedRIS
Clinical software See Adverse Events

InfoPro Solutions
Clinicopia Suite
The Clinicopia Suite is the world’s first purpose-built, industry-specific clinical trials supplies management system developed from the ground up to meet the unique needs and concerns of all the groups associated with clinical trials materials supply. The Suite consists of Clinicopia Supply Chain, Clinicopia Drug Accountability, Clinicopia Process Execution, Clinicopia Labeling, and Clinicopia Forecasting.

Integic Corp.
Clinical Trials Management System
Our clinical trials management system is a browser-based tool for end-to-end clinical trials management. Through a user-friendly, intelligent interface, you can configure studies, enroll investigators and patients, track visits, and much more.

KIIKA Medical
Events Suite See Clinical Project Management

NetRegulus
NetRegulus v6
NetRegulus v6 includes a comprehensive set of business process solutions that allow users to collect, analyze, report, share, and act on critical regulated data within one streamlined, 21 CFR Part 11 compliant package. Our Study Data Management solution features intuitive tools to enter, track, verify, query, view, and export case report form data as well as input and oversee key management information. Available with sophisticated EDC and RDC utilities.

Oestreich & Partner GmbH
CRO Services See Adverse Events

Outcome Sciences
Outcome Project Management See Clinical Project Management

Perceptive Informatics, Inc.
IMPACT
IMPACT is the market leader in Clinical Trials Management Software. It is designed to assist pharmaceutical companies, CROs, device manufacturers, and biotech companies in managing research activities—ranging in scale from single site to large multinational, multisite studies, and from first use in man to single or multi-country marketing studies. IMPACT will give you total flexibility in the level of detail tracked, while maintaining complete consistency across the user base. IMPACT is integrated with a range of other applications, including IRRS, Financial, Portal, and Web Tracking systems.

Perceptive Informatics, Inc.
INITIATOR See Data Collection and Management

PerMedics, Inc.
Surveyor Trial Management System
Surveyor is a software application designed for single and multisite clinical trials management. Surveyor tracks trial progress including enrollments, patient status, resource management, financials, and IRB activity. Patient tracking tools include automated scheduling, screening, adverse events and visit completion reports. The Web-based software aids HIPAA compliance and simplifies trial management with unlimited reporting capability. PerMedics’ software suite includes data capture solutions and services.

PharmaNet
Services See Adverse Events

PharmaTech Solutions, Inc.
Patient Recruitment, Interactive Voice Response Systems, Outcomes Research Implementation Support, Consumer Affairs Support See Other Applications

Phase Forward
Data management solutions
Phase Forward is the leading provider of integrated data management solutions for clinical trials and drug safety. We are dedicated to helping pharmaceutical, biotechnology, and medical device companies bring needed drugs and therapies to market faster and more safely. Phase Forward offers proven solutions in electronic data capture (EDC), clinical data management (CDM), and adverse event reporting (AER). Phase Forward products and services are used by 11 of the top 15 pharmaceutical companies and...
more than 300 organizations worldwide. See *Adverse Events,* "Data Collection and Management," and "Electronic Data Capture."

**Propack Data**  
PMX(R) CTM Solution See Clinical Project Management

**Sierra Scientific Software, Inc.**  
Clinical Research Information System (CRIS), v7.1  
The Clinical Research Information System (CRIS), v7.1 provides a fully integrated, fully interactive application that captures, archives, and reports data across the entire clinical enterprise. Supporting electronic or manual entry and export of data, CRIS incorporates COM, CTMS, materials management, and safety data management and accelerated reporting functions.

**TrialTrac, Inc.**  
TrialWorks  
TriaWorks is clinical trials management software designed for sponsors and CROs. It's easy to use, quick to implement, customizable, and 21 CFR Part 11 compliant—which may explain why, since our founding, TrialWorks has been installed by more companies than any other CTMS product, and is also available as a hosted application through our e-Service.

**TrialTrac, Inc.**  
SiteTrac  
SiteTrac is clinical trials management software tailored to the needs of SMOs, research institutions, sites, and ARCs. It's easy to use, quick to implement, customizable, and HIPAA compliant. Our integrated design is comprehensive, and tracking includes patient information, essential documents, investigator earnings and sponsor payments, patient/study searching, and every step in between.

**Velos, Inc.**  
Velos eResearch  
Velos eResearch is a transformational trial management solution that supports investigators, study teams and sponsors through the entire research process—including protocol design, patient feasibility assessment, study administration, project management and trial execution—thus expediting the research process, enhancing quality and improving access to data by integrating systems, aggregating information and centralizing processes.

**Waiife & Associates, Inc.**  
Process Change See Custom Application Development

**Winchester Business Systems, Inc.**  
Winchester's Protocol Manager  
An Internet-based CTMS designed to assist pharma, biotech, and CROs manage all aspects of multi-country clinical trials. Protocol Manager is configured to manage different business and management rules for all trials. Integration with Microsoft Word, Excel, and Project and Oracle-based Data Management Systems allows for the ultimate flexibility. Winchester implements systems for multi/siite/multi-vendor clinical trials projects.

**Validation**

**Analyse-It Software, Ltd.**  
Analyse-It Clinical Laboratory See Statistical Analysis

**Assured Information Systems**  
PV-Works See Adverse Events

**Biomit, Inc.**  
Services See Adverse Events

**BioPharm System, Inc.**  
Validation and Compliance  
BioPharm Systems’ validation experts can perform complete validation (including IQ, OQ, and PQ) of your applications based on FDA and other regulatory standards. We offer complete 21 CFR Part 11 assessments of your systems environment: identifying compliance gaps, developing a plan to bring your applications into compliance, and assisting with remediation efforts. Also, we offer a 21 CFR Part 11 requirements training course.

**DataCeutics, Inc.**  
IT Support and Services for the Clinical Research Environment See IT Consulting

**Honeywell/POMS**  
POMS CMS See Trials Management and Administration

**iMedRIS**  
Clinical software See Adverse Events

**Insightful Corp.**  
Validation See Custom Application Development

**PharmaNet**  
Services See Adverse Events

**Phase Forward**  
Computer System Validation (CSV) Solution Suite  
Phase Forward's Computer System Validation (CSV) solution suite is a set of service offerings that reduces the cost, effort, and risk associated with certifying that a computer systems' platform and work processes are reliable, secure, and adhere to regulatory standards. Developed by Phase Forward's technical and clinical experts who designed a framework for installation, operational, and performance qualification validation for different customer needs, the CSV solution suite enables customers to utilize Phase Forward's software productively with a shorter time lag between purchase and launch.

**Relsys International, Inc.**  
Argus Safety  
Relsys International is the leading developer of specialized software for managing product risk associated with pharmaceuticals and medical devices. The company's software solutions empower manufacturers to meet current product safety regulations and internal quality objectives. Argus Safety is the world's top-selling global drug safety software solution.

**SEC Associates, Inc.**  
Computer system compliance consulting  
SEC Associates provides system compliance consulting and computer validation services for the pharmaceutical, biotechnology, and medical device industries. SEC's experienced consultants assist clients with regulatory compliance assessments, vendor audits, 21 CFR 11 training, procedure development, requirements analysis and planning, documentation, and execution of computer validation and life cycle activities.

**StudyBuilder Limited**  
Inside StudyBuilder See Training

**Synapse**  
Synapse VT  
Jump-start your computer systems compliance project with this comprehensive toolkit. Delivered by its internationally recognized expert consultants, Synapse works in partnership with your organization to deliver highly effective and efficient consulting services across the entire GxP scope (GMP, GCP, GLP).

**Winchester Business Systems, Inc.**  
ComPac GxP  
ComPac GxP software from Winchester Business Systems is the only complete 21 CFR 11 solution for Lotus Notes and Domino. It allows an organization to make its existing or future Notes-based applications 100% compliant with 11 regulations. ComPac GxP bolts on to the existing applications with minimal disturbance to the original code.

**Web-Based Software**

**Acumen Healthcare Solutions, LLC**  
Tracit2k EDC System See Electronic Data Capture

**Aris Global**  
globalTRIALS See Trials Management/Administration

**Biomit, Inc.**  
Services See Adverse Events

**ClinicalTrialsNet, Inc.**  
CliniNet See Data Collection and Management

**ClinLogic**  
Services See Custom Application Development

**ClinPhone**  
Data collection See Data Collection and Management

**Dynarand**  
Integrated Study Management  
Dynarand's Interactive Voice Response (IVR) and Web-based Systems provide integration of real-time data to simplify project management, reduce human error, and save time and money. Automated notifications and summary reports provide the additional tools that make the system an optimal solution for study management.

**ePharmaLearning**  
eMeetings, eLearning  
ePharmaLearning is a clinical performance improvement company that has improved site performance through innovative site feasibility and protocol training solutions for 7 of the 10 largest pharmaceutical companies in the world. Our solutions will help reduce data queries, improve site performance, predict the sites most (and least) likely to succeed in a study, and will help verify the best possible recruitment strategy at a SiteCentric level. ePL online sessions can be delivered at 70% of the cost of in-person meetings.

**etrials Worldwide, Inc.**  
See Clinical Project Management

**Formedix, Inc.**  
Formedix Express  
Two innovative EDC solutions which can be delivered on-line, off-line, distributed, mobile and wirelessly, and are applicable in any clinical environment. Unique Phase I solutions facilitate real time concurrent data entry enabling rapid throughput of subjects. Data values can be exported to a populated ODM file ensuring full portability of clinical data now and in the future.

**GEREQ**  
See Custom Application Development

**Hyphen**  
INSPIRE See Custom Application Development

**iMedRIS**  
Clinical software See Adverse Events

**Insightful Corp.**  
Services See Custom Application Development

**Integic Corp.**  
Clinical Trials Management System See Trial Management and Administration

**Integic Corp.**  
CRF WorkManager Web Module  
The Web Module leverages the Web for global access and processing of clinical trial information across remote locations. You can search, check in, check out, and add documents from any location into CRF WorkManager via the Web. For CRF WorkManager details, see Data Collection and Management.
Keris, Inc.  
VitalTree See Electronic Data Capture

LifeTree—Clinical Services from FFF  
LifeTree ICTM 4.0  
LifeTree is accelerating clinical development, from data capture to market, with exceptional clinical services and electronic data capture. LifeTree ICTM 4.0 meets your Web-based study management challenges with enhanced eCRF navigation, data on demand, real-time access to information and skilled project management. Since its founding, LifeTree has grown steadily, backed by the stability of parent company FFF Enterprises, a national leader since 1988 in biopharmaceutical management and specialty pharmacy services.

MAJARO InfoSystems, Inc.  
ClinAccess Web  
Coming this year, data entered via Web directly into SAS datasets. Uses PDF, with online validation. Serves data back (available dynamically as entered) for review, reporting. Data clarification processing, including query resolution and tracking, with dynamic access to images. Easily combine data from Web, OCR, and/or in-house entry.

Medidata Solutions, Inc.  
Medidata 4sight  
Medidata 4sight joins the core technology philosophy of Medidata’s clinical research products with opportunities for online communications packages for post-approval trials and registries. Online newsletters, surveys, forums, and downloadable or linked content (such as white papers, Webcasts, and other resources) are prebuilt and ready for rapid branding and deployment with trial-specific content.

Medidata Solutions, Inc.  
Medidata RAVE See Electronic Data Capture

OmniComm Systems, Inc.  
TrialMaster See Electronic Data Capture

Outcome Sciences  
Outcome 7.0 See Electronic Data Capture

Perceptive Informatics, Inc.  
INITIATOR See Data Collection and Management

PerMedics, Inc.  
Surveyor Trial Management System See Trials Management and Administration

PharmaNet  
Services See Adverse Events

PharmaPros Corporation  
NCOMP See Data Collection and Management

Phase Forward  
Software services See Electronic Data Capture

Phoenix Data Systems  
IT Applications See Data Collection and Management

Scientific Software Tools, Inc.  
VISTA See Clinical Project Management

StudyBuilder Limited  
MyStudyBuilder.com  
MyStudyBuilder.com ($4999 per quarter)  
MyStudyBuilder.com is the one stop data hosting service for studies designed with StudyBuilder software. Locate at MyStudyBuilder.com and your study will have a private Web site built and deployed on dedicated servers within a few hours.

Synapse  
RegTracker See Knowledge Management

Velos, Inc.  
Velos eResearch See Trials Management and Administration

Waife & Associates, Inc.  
Process Change See Custom Application Development

**Wireless and Mobile Technology**

Aris Global  
ClimTALK  
Enables companies to easily connect to other disparate systems (e.g., COMS, safety, financial, and other systems) in order to share critical information in real-time.

Clarinet Systems  
EHR LAN  
The EHR LAN family brings PDA and laptop users the immediate benefits of dedicated high speed network access using popular software applications such as AvantGo, Web clippings, Eudora Web browsing, E*Trade stock transaction, email access, etc. Installation of the EHR LAN into a 10/100 Base-T or 802.11b backbone for network access is seamless due to its internal DHCP functionality.

Clinitrac  
Clinitrac Patient Diary, Clinitrac Visit Diary See Electronic Data Capture

ClinPhone  
Data collection See Data Collection and Management

Formedix, Inc.  
Formedix Express  
Our suite of next generation EDC systems works in all phases of a clinical trial. These innovative solutions can be delivered on-line, offline, distributed, mobile and wirelessly and are applicable to any clinical environment. Unique Phase I solutions facilitate real time data entry using wireless tablet PCs enabling high volumes of data to be captured by teams of people concurrently.

GEREQ  
See Custom Application Development

Hyphen  
INSPIRE See Custom Application Development

Integic Corp.  
Pen-based data capture  
Integic uses leading-edge technology to ease the burden of change with pen-based data capture. A digital pen and paper capture each stroke to create an electronic image enabling optical recognition and auto-indexing technologies. This is possible with anything from handwritten case report forms to lab notes.

invivodata, Inc.  
invisystem See Data Collection and Management

Logos Technologies Ltd.  
SMART Patient Diary Card  
Logos Technologies is a global provider of System Solutions for Drug Research to the world’s Pharmaceutical and Clinical Research Organizations. Our market leading products, ALPHADAS and Smart Patient Diary Card have successfully improved our clients study efficiency, provided compliant data, achieved a faster database closure, as well as dramatically reducing cost. Logos Technologies prides itself on its high quality solutions which meet GCP & FDA regulatory compliance such as 21 CFR 11.

NetRegulus  
NetRegulus v6 See Electronic Data Capture

Outcome Sciences  
Outcome 7.0 Mobile  
The Outcome system is integrated with Palm and Personal Digital Assistant (PDA) data capture systems for easy access at the point of care. Additionally, it is available as Outcome Offline, for users who need to access the system while disconnected from the Internet.

Phoenix Data Systems  
IT Applications See Data Collection and Management

PHT Corp.  
ePRO Solutions See Data Collection and Management

**Scientific Software Tools, Inc.**  
VISTA See Clinical Project Management

StudyBuilder Limited  
StudyBuilder Enterprise Edition See Electronic Data Capture

Vitalograph, Inc  
Electronic PEF/FEV1 Diary system See Electronic Data Capture

**Other Applications**

ClinLogic  
Patient Registries  
ClinLogic provides custom patient registry design, development and validation for FDA mandated post marketing surveillance.

Dynarand  
Electronic Diaries See Electronic Data Capture

Dynarand  
Integrated Study Management See Web-Based Software

Hyphen  
INSPIRE See Custom Application Development

iMedRIS  
IRB software See Adverse Events

Outcome Sciences  
OutReach  
OutReach is the first Web-based survey system specialized for medical practitioners. It can be used in combination with Outcome 7.0 to survey existing registry/study participants, or as a stand-alone Web-based survey system. It is ideal for market or opinion research surveys. Sponsors can provide their own panel lists or utilize existing standing physician panels (e.g. primary care, neurosciences, etc.)

PharmaNet  
Services See Adverse Events

PharmaPros Corporation  
CRFTrack See Data Collection and Management

PharmaPros Corporation  
DataVal  
DataVal is a suite of flexible, validated, easy-to-use PL/SQL programs for use in the design and development of edit checks. Using DataVal can significantly reduce the effort in the development and testing of edit checks, and increase consistency across studies for discrepancy management. DataVal is integrated with Phase Forward’s Clinktrial 4.

PharmaTech Solutions, Inc.  
Patient Recruitment, Interactive Voice Response Systems, Outcomes Research Implementation Support, Consumer Affairs Support  
PharmaTech Solutions is a Patient Management Organization (PMO) serving the pharmaceutical and healthcare industry. We pride ourselves on focusing on the patient in clinical and commercialization programs. We provide services that accelerate enrollment of thoroughly qualified patients and maximize patient compliance and retention. Our clinical and marketing experts understand disease states, the challenges of enrolling a clinical trial, the importance of collaboration with investigator sites and our responsibility in educating and communicating with patients.

Phoenix Data Systems  
IT Applications See Data Collection and Management

SEC Associates, Inc.  
Computer system compliance consulting See Validation

Waife & Associates, Inc.  
Process Change See Custom Application Development