

Late Phase Focused Technologies

Technology

REGISTRAT-MAPI technologies can be seamlessly integrated, as project requirements dictate, to provide optimal project-specific solutions.

REGISTRAT-MAPI IT professionals research new technology and evaluate ways to enhance current technology for ease-of-use in clinical studies. Our IT developers and support staff bring extensive experience to guide requirements and implement technologies for large clinical and observational studies. That experience has allowed us to build a broad platform that includes project-specific Internet portals, Electronic Data Capture (EDC), OCR/ ICR fax scanning, Interactive Voice Response System (IVRS), and a proprietary site management system, REGISTRAK®.



REGISTRAK®

The developers at REGISTRAT-MAPI, in strategic cooperation with other departments at REGISTRAT-MAPI, designed, developed, and deployed a Site Management System designed specifically for the requirements of Late Phase studies. This product has evolved since 2001 into REGISTRAK®, a Web-based solution for tracking internal and external communications, collection and processing of regulatory documents, monitoring site and patient enrollment metrics, tracking training documentation, and much more! REGISTRAK® is a single source for enrollment information and other pertinent study information, and integrates workflow across REGISTRAT-MAPI functional departments.

REGISTRAK was developed using a variety of Microsoft® technologies. The base application was built with flexibility in mind, providing security levels and a custom experience to give the end user access to the information necessary to complete their tasks. REGISTRAK® is built to run easily in MSIE browsers and requires no special hardware or software—just an Internet connection. REGISTRAK® has been fully validated in accordance with 21 CFR part 11 and ICH and GCP guidelines. REGISTRAK® version 4 includes enhancements based on REGISTRAT-MAPI processes and typical requirements of Late Phase studies. REGISTRAT-MAPI can provide access and use of REGISTRAK® to sponsors to create a seamless team working environment.

EDC System Design / Implementation

The REGISTRAT-MAPI Data Management group will design and implement REGISTRAT-MAPI EDC based on study-specific EDC requirements developed in cooperation with the sponsor and REGISTRAT-MAPI professionals. Detailed information on EDC design is covered in the Data Management section.

Electronic Patient Reported Outcomes (ePRO) Solutions

Depending on study requirements, REGISTRAT-MAPI can use multiple technologies to collect PRO data. REGISTRAT-MAPI's Web-based ePRO system allows users to enter data in an interview based format. Behind the interview is a complex data collection system that integrates an easy-to-use form with simple to complex error checking, tree guided interview paths, automatic notifications, and rapid setup features.

Interactive Voice Response System (IVRS)

REGISTRAT-MAPI's IVRS integrates state-of-the-art information systems and computer and telecommunications technologies to provide a scalable solution that can be combined with other REGISTRAT-MAPI technologies. Our combination of technical expertise, clinical research experience, and IVRS experience allows us to provide centralized randomization, collection of patient reported outcomes, and drug management services for Late Phase studies and registries, as well as other applications that may be needed in the course of a study.

Patient Reported Outcomes (PRO)

The IVRS allows patients to enter study-related diary information or complete PRO instruments using a touch-tone telephone. Given the prevalence of telephones this is a preferred data collection method for patient reported outcomes. Typically, study sites enter or initialize enrolled patients into the IVRS, following which, patients can begin to enter diary information or complete PRO instruments.

Event Reporting

To streamline the reporting of specific events throughout the course of a study, such as serious adverse events, IVR can be used as a trigger to initiate manual processes or use of other technologies. The IVRS can receive information that can be triaged at REGISTRAT-MAPI, automatically sent via fax, or entered for review. Using multiple integrated technologies, processes can be streamlined and events tracked with a high degree of timeliness and accuracy.

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REGISTRAT-MAPI Electronic Data Capture

REGISTRAT-MAPI uses a comprehensive, flexible, and 21 CFR part 11 compliant system designed to create efficiencies in the work flow process for clinical studies, enhance data accuracy, and in doing so, accelerate clinical study timelines. The Data Management module includes an eCRF creation tool, Designer Work Bench (DWB), the industry's simplest drag and drop graphical tool. DWB enables data management professionals to easily design case report forms, create data validation rules for automatic edit checks, define code or decode lists, and automatically configure underlying database schema corresponding to each form. This process that typically takes six to twelve weeks can be done more expeditiously using DWB, depending on form elements, data cleaning strategies, and field types identified in the eCRF development process.

Key features of the REGISTRAT-MAPI EDC system include:

- Customizable user interface allows for sponsor or study-specific branding.
- Flexible eCRF design capabilities make data entry more intuitive.
- eCRF screens are set up for ease of entry, incorporating drop down boxes, check boxes, radio selection boxes and dynamic fields to reduce data entry errors that can generate queries.
- Conditional form flow can be set up on a field or page level to allow for tree based entry of data
- Pre-populated fields can be set up to eliminate redundant data entry.
- eCRF Completion Instructions are created as an online help tool.
- Online edit checks provide immediate feedback to the user if data is missing, out of range, or inconsistent with other data entered. Query management workflow can be designed to meet the specific needs of each study.
- User comments can be sent to a monitor for review in the field, so they can resolve queries and issue manual queries.
- CRF printing instantly generates printed images based on user need.
- Sponsor-defined study status reports are designed to provide real-time study metrics, such as patient enrollment counts and query management statistics.
- Data can be accessed real time through the use of custom reporting and dynamic charting modules that may include aggregate and blinded site and patient data. Data can be presented in Excel, PDF, or html format.
- Data transfers can be regularly scheduled via SAS transport files, SQL, text files, or specialized formats, as required, and as pre-determined according to sponsor specifications.
- Secure audit trail stores the previous value of altered data, user name, date, and time of change.
- Compliant with all requirements of key industry regulatory guidelines and computerized clinical data management conventions, including 21 CFR Part 11, ICH-GCP, and HIPAA.

REGISTRAT-MAPI EDC is based on thin client architecture, and thus, requires no installation or downloading for study sites, participants, or the Sponsor. The core EDC solution, accessed via a secure Web page, includes customizable Web-based data entry screens, query management, built-in reporting capabilities, and a host of communication and reminder features. It is designed to provide quick study start-up and powerful, flexible, on-going study administration.

The application is accessible via any system capable of supporting a mainstream browser with a connection speed of at least 56 kbps. REGISTRAT-MAPI EDC is a hosted application that features state-of-the-art physical and technological security to provide a tested, secure, and reproducible environment for data collection and storage.

Fax Scanning

REGISTRAT-MAPI's fax scanning system consistently delivers quality data using an established methodology. Sites will appreciate the ability to fax Enrollment Forms directly into REGISTRAT-MAPI and experience fast turnaround as they are imported into the REGISTRAT® Site Management System. Enrolled sites can fax Case Report Forms (CRFs) to REGISTRAT-MAPI for integration into REGISTRAT-MAPI's Clinical Data Management System (CDMS).

REGISTRAT-MAPI's highly skilled Data Management group can create customized forms for high-speed scanning or fax receipt based on study requirements. Scannable forms use anchor points to define fields, field types, and form flow. Forms can be disseminated to sites by mail or via a secure Internet portal.

Once forms are deployed, REGISTRAT-MAPI maintains both fax server capabilities and high-speed scanners to receive images. These images are exported to both the Optical/Intelligent Character Recognition (OCR/ICR) system and to REGISTRAT-MAPI's imaging system.

The OCR/ICR system software interprets the images and automatically performs OCR/ICR extraction, highlighting questionable entries to be reviewed by an operator. All fields are 100% verified to ensure completeness and accuracy of the database. Because the OCR application processes the majority of the information, entry operators spend seconds verifying questionable data rather than minutes manually keying entire forms.

Technology plays a significant part in a successful fax scanning system. REGISTRAT-MAPI's dedicated fax servers are available 24/7 for sites to fax CRFs or other data to REGISTRAT-MAPI. Our OCR/ICR system resides on redundant servers to ensure that information is processed quickly and efficiently. REGISTRAT-MAPI's OCR/ICR system is hosted in REGISTRAT-MAPI's secure hosting facility.

Data Visualization Technology

Visualizing data trends during the course of a study is a significant added value to both Sponsors and Investigators. REGISTRAT-MAPI's Data Visualization Technology (DVT) provides graphical and tabular data views and common format exports on active study data. This data visualization capability may be accessed from a study-specific Internet portal or in conjunction with a data collection technology such as EDC. REGISTRAT-MAPI can create a custom data visualization environment using a core set of technologies for delivery over the Internet.

Investigators will find the patient profile capabilities of the DVT to be a valuable practice management tool. Investigators can monitor individual patients, groups of patients, or all of their study patients over time and provide patients feedback on their personal study data. DVT is designed to facilitate review of longitudinal study data such as medication use, demographic characteristics, and outcome measures. Investigators can create pre-defined views that provide a convenient starting place for customized data visualization or they can modify data views according to their specific interests. Investigators can choose graphs to appear at start-up and can add, remove, or re-arrange graphs at any time.

Sponsors will find the ability to create custom graphical views on aggregate data extremely useful in monitoring emerging data trends in a study. DVT enables a user to create custom data views based on selected data criteria. The user can view all or selected study variables, sort and re-arrange data, create criteria to subset data, summarize data with descriptive statistics, and create custom graphs. DVT provides sorting, grouping, and graphing of data, allowing researchers to visualize and explore relevant clinical data and identify topics for further analysis.

REGISTRAT-MAPI's programmer analysts and statisticians can generate custom analyses and reports of study data for Sponsors and Investigators. For more information on these services, please refer to the Statistical Programming and Biostatistics sections of this brochure.

Data Protection and Disaster Recovery

All REGISTRAT-MAPI Technology systems are backed up as outlined by SOPs that govern electronic data back-up and recovery procedures. Multiple robotic libraries handle tape backups which are rotated to secure off-site locations as required. For business critical and clinical systems individual Disaster Recovery Plans (DRP) are created to address potential disasters.

Hosting

REGISTRAT-MAPI's secure server room is a raised floor, 1100 square foot, climate controlled facility which boasts multiple UPS redundancies as well as a full 480 KVA generator in case of power emergencies. Multiple internal and external monitoring systems proactively alert REGISTRAT-MAPI system administrators of potential issues, thus assuring a high percentage of uptime. Applications in the hosting center can be deployed in a secure DMZ, a segregated sub-network, or in any other manner necessary to facilitate maximum security and uptime on dedicated or shared hardware.

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Portal Technologies

REGISTRAT-MAPI develops project-specific Internet portals to manage communication and information and support ongoing logistics and operations of a study. An Internet portal can provide a seamless interface among the sponsor, REGISTRAT-MAPI, the Scientific Steering Committee, Investigators, and Study Coordinators. A study portal can provide additional branding support for a program, facilitate site relationship management via REGISTRAK®, disseminate program information (protocol, CRF, data reports, newsletters, etc.), track site and patient enrollment metrics, and create an interactive sense of community among study participants.

REGISTRAT-MAPI uses a custom portal engine to deploy the portal solution. This solution was built by developers to create a living application that can be customized as necessary to meet the needs of the project. REGISTRAT-MAPI developers can assist in creating the Web presence necessary to assist in building a growing online community or a solid project presence. REGISTRAT-MAPI's portals are deployed in our secure hosting facility.

Virtual Private Networks

To facilitate consistent secure communication between a sponsor and REGISTRAT-MAPI, a VPN tunnel can be established. This tunnel can use low to high encryption and allows for secure transmission of study files, images, study information, data reports, and email. In setting up VPN connections with sponsors, REGISTRAT-MAPI segregates necessary servers using routing tables and appliances as necessary. Tunnels are monitored constantly to ensure uptime and allow companies to function as a seamless unit. REGISTRAT-MAPI Information Technology will work with a Sponsor or partner to establish guidelines, set requirements, set contingencies and create the monitoring points to achieve success. Once the VPN is implemented it is transparent to all end users and allows normal use of all Internet applications while securing data transmissions between the companies.

Validation and Testing

REGISTRAT-MAPI validates technologies to maintain compliance with appropriate regulatory guidelines. SOPs guide Validation Specialists working in cooperation with REGISTRAT-MAPI's QA Department to ensure proper standards are met or exceeded. The REGISTRAT-MAPI Software Development Lifecycle allows for flexibility in the creation of new systems while maintaining a high level of quality.

FDA (21 CFR Part 11), Electronic Signature Compliance

Required systems are developed, validated and maintained in compliance with the FDA's Proposed Rule on Electronic Signatures (21 CFR Part 11), Electronic Records. REGISTRAT-MAPI also validates in accordance with regulatory guidelines.



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