



AS A HEALTHCARE-RELATED ORGANIZATION, FDA REGULATIONS AND FEDERAL LAWS REQUIRE YOU TO IMPLEMENT COMPLIANCE SYSTEMS AND STRUCTURES. IN SOME SITUATIONS, SUCH AS IMPLANTED DEVICES AND CLINICAL STUDIES, COMPLIANCE REQUIRES THE TRACKING OF INDIVIDUAL PATIENTS. BUT TRACKING PATIENT INFORMATION IN DETAIL IS COSTLY, TIME-CONSUMING, AND CONSTANTLY REQUIRES YOUR PROACTIVE ATTENTION. THE LACK OF A ROBUST, SECURE, PROCESS-DRIVEN APPROACH CAN SERIOUSLY AFFECT YOUR PROGRAMS AND ASSOCIATED FUNDING.

SCANTRON, A LEADER IN THE RAPID, ACCURATE AND RELIABLE CAPTURE OF DATA, OFFERS A COMPLETELY OUTSOURCED PATIENT TRACKING SOLUTION FOR WHEN YOU MUST TRACK YOUR PATIENTS WITH THE HIGHEST DEGREE OF RELIABILITY. SCANTRON'S SOLUTION (REAL-WORLD AND PROVEN OVER YEARS AND MILLIONS OF PATIENT RECORDS) CAN SATISFY YOUR REGULATORY REQUIREMENTS SECURELY, EASILY, AND AUTOMATICALLY— FREEING YOUR ORGANIZATION TO FOCUS ON ITS CORE MISSION.

End-to-End Solution

Scantron's Patient Tracking solution records, maintains and updates contact information for patients and their physicians. It starts with capturing and storing initial paperwork then follows patients' activities for the following years. Our sophisticated process and technology infrastructure constantly updates and verifies patient information and appends new patient-related events. Individual patient records actively link to all images, documents, and event information which can be easily retrieved later via Scantron's robust reporting capabilities.

Outsourced Compliance

By combining technology and highly-trained staff, Scantron tracks compliance against established FDA or other required reporting metrics. Scantron's solution is flexible to meet your specific needs:

- Addresses specific market- or program-related interpretations of FDA guidelines
- Satisfies needs beyond FDA requirements such as sales and marketing activities, situational event analysis, and patient communications
- Supports a number of stakeholders including patients, physicians, hospitals, and sales and marketing staff.

Scantron's solution includes quality checks, performance monitoring measurements, and alerts to ensure ongoing reporting compliance. Supporting services include forms and mail handling, document scanning and indexing, data management and call center transactions.

Broad Applicability

Scantron's infrastructure can be applied to a number of patient-tracking needs, including but not limited to:

- Clinical studies
- Immunization
- Childhood diseases



A Proven Solution

Scantron has applied its Patient Tracking solution to real-world situations for years. One of the leaders in implanted medical devices currently depends on Scantron's outsourced solution to track millions of patients and their implanted devices to achieve highly accurate FDA compliance with reasonable cost.

The manufacturer is passionate about fulfilling FDA requirements to track these devices, yet it wants to keep its own staff focused on the company's core mission. The outsourced solution from Scantron is the perfect balance between compliance and efficiency. Scantron automatically and proactively registers new patients, tracks events and patient changes to maintain each individual patient record, and provides full reporting services to the manufacturer – all at a fraction of the cost if such tracking had been handled internally.

The first step in the tracking process for this manufacturer is a patient registration.

This first registration generates a number of downstream transactions to be handled by Scantron. A key aspect of Scantron's medical device tracking solution is the constant verification and authentication of patient data against other records and data sources. Scantron's TRaC II system includes multiple checks to prevent erroneous data from being entered and generates system flags when inconsistent data is detected. For example, one automatic check verifies that the serial number for a device to be registered has, in fact, been shown as a shipped device from the manufacturer. There are a multitude of similar automatic checks built into the system.

Once a patient has been registered into the system, Scantron's solution ensures their information remains up to date and valid. If a patient record has changed or is missing information, multiple online resources are consulted to correct the records. If those resources are insufficient, the issue is handed to an investigative team. This team uses

alternative data sources such as external databases, phone, fax, mail, and email to proactively reach out to the patient and/or physician and validate the latest information. The TRaC II system provides the process, workflow, and data storage for the entire approach.

The sophisticated TRaC II system also automatically generates transactions and/or produces alerts, correspondences or other required actions. For example, TRaC II can automatically produce verification letters that are then mailed to constituents. The system then tracks responses to the verifications and prompts Scantron staff if further action is required.

Overall, Scantron's device tracking system – built on the technology and process of its TRaC II technology – saves this manufacturer millions of dollars in direct expenses, provides extremely high levels of quality and services, and allows the manufacturer to remain fully compliant while keeping its internal staff focused on the core business.

Tracking Patients with Implanted Devices

- Scantron's systems handle registration information related to devices, patients, facilities, physicians, and sales representatives.
- Scantron's systems manage ongoing data for over 20 million patients, images, and devices combined.
- Scantron supports approximately 100,000 transactions per month.

For more information, visit us at healthcare.scantron.com or contact your Scantron Healthcare representative:
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