



CLINICAL DATA COLLECTING SERVICES WITH DIGITAL PEN&PAPER

The technology

The Digital Pen&Paper's introduction is a unique forward step in electronic communications: in fact it combines the PC's digital world and the traditional world of paper and pen.

Using this application is as easy as using normal pen and paper. The main differences are that the paper has a special pattern printed on it and it requires the use of a digital pen for writing and drawing on it.

Both the processing and transmission of handwritten text and images are based on the **Anoto Functionality**: a special digital pen (provided with a **special optical reader** which makes it possible to acquire and to memorize data while writing) and a paper (also NCR) printed with a **pattern invisible to the eye**, which accurately conveys to the pen **handwritten information**. Advanced image processing and a complex infrastructure allow written data to be transformed to digital media.

The Digital Pen's software sends information to the computer, where it is turned into digital format and then it can be easily organized, shared and stored.

_ The paper

A specific process prints the CRF on ordinary paper and inserts a special identification pattern (invisible to the eye), which allows the pen to identify it and to recognize the handwritten information.



_ The pen

When writing with normal ink, an optic sensor on the top of the pen makes it possible to acquire and to memorize data and takes in what is written in the CRF fields.

_ The cradle

By placing the pen in its rechargeable holder (cradle: connected via USB to the Personal Computer) the data is transferred via Internet to a central server for acquisition and management.

_ The handwriting recognition

Handwriting recognition transforms handwritten text into a digital text format, which can then be used by computers.

_ The data management

The handwritten information received in real time and memorized on the central server, can be elaborated in the several configurations of the **ink data** service.



The ink>data services

The ink>data services use the innovative Digital Pen&Paper technology to offer new methods for the collection and management of clinical data: **the handwritten CRF is automatically transmitted via internet and made available to the users in various digital formats.**

GM is a software house and a technical structure specialized in providing services for pharmaceutical research with web based information systems.

GM know-how has proved highly successful in the field of software development, of technical management of computer systems and validation/quality control.

GM offers Digital Pen&Paper technology in the **Service Provisioning** mode with various configurations **organized according to increasing service stages:**

- _ Stage 1 – **Image Collection**
- _ Stage 2 – **Image Recognition**
- _ Stage 3 – **Data Validation**
- _ Stage 4 – **Full Clinical Data Management**

Stage 1 – Image Collection

The basic configuration of the **ink>data** services (**Stage 1 - Image Collection**) involves **access via internet to the repository of the images and completed forms/folders.**

In fact, the writing acquisition process allows users to obtain real time images of the CRF as forms are being filled in. In addition, a detailed record of the time data has been entered is provided.

With this service the user will then be issued specific accounts to access via Internet the storage system of the images received from the pens, as well as the interaction with the sophisticated time and space tracking of the writing in each individual page of CRF.

The use of the ink>data services, in this basic configuration, optimize the time required for clinical data acquisition, without burdening the Investigator with the necessity of interacting with a Remote Data Entry system.

In fact, each single registration can be sent to the central system by placing the pen in its cradle, in real time, or at any subsequent moment, consistent with the Monitor's needs. This can be done without the inevitable waits due to the collection of the original "source documents" from the various centers.



Stage 2 – Image Recognition

The **Stage 2 - Image Recognition** configuration of the **ink>data** services include the **conversion/recognition (with a quality process) of the graphic information received from the pen, into digital data** suitable to customer's backend processes.

The service includes the execution of needed automatic and manual procedures for the recognition of the images (as made available in the Stage 1 - Image Collection configuration of the service) in data available in a database, or in any other common interchange format (**TXT; XML; Excel; Access; etc.**).

This configuration is **particularly suited for observational clinical studies** which involves qualitative levels that are not absolute and **can fully benefit from the collection speed and a process of data recognition** that guarantees the match between the data in the data base and the data received from the Investigator's pens.

Stage 3 – Data Validation

The **ink>data Stage 3 - Data Validation** configuration includes the completion of the recognition process included in Stage 2 of the service, **with the final validation of the data obtained through a final comparison with the information present in the paper source document (CRF) with the data present in the exportable data base.**

In Stage 3 of the **ink>data** services take place the verification of the data stored in the system with all the information written on original paper, after the collection of the original handwritten source documents at the sites.

The final comparison of the data detected through the pen with the actual paper “*source documents*” collected at the centers, including **all of the formal quality control procedures and corresponding Validation protocols**, allows for combining the speed of acquiring the provisional data with the usual (and generally accepted) procedures for management and validation of a clinical study on paper carried out in the traditional manner.

Stage 4 – Full Clinical Data Management

The most advanced configuration of the **ink>data** services (**Stage 4 - Full Clinical Data Management**), integrate the phases of acquisition, transfer, graphic storage and exportation of the data received from the pens, with a complete and tested web-based system for data management of clinical research.

The service includes the availability of a suitable multi-study, multicenter, *web-based* system for the customer, which can be configured according to the needs of each individual protocol. It includes many modular functions for the management of **data cleaning, queries, safety, data export, reporting, logistic-administrative tracking, etc.**



The Stage 4 - Full Clinical Data Management configuration therefore represents a complete solution which, through the use of a CTDMS system which has been **tested, validated and integrated with Digital Pen&Paper technology**, proposes to fully meet the needs of a pharmaceutical company engaged in clinical research.

The advantages

The Digital Pen&Paper's use in the Clinical research studies ensures the **biggest freedom and competence** in ward or in ambulatory because the operations of data collection may be carried out far from the computer.

In fact during the medical inspection it is possible to fill in the CRF simply writing on the apposite printed form.

Later on, it is sufficient to link the pen to a computer in order to convey automatically the information to the central system.

Thanks to the integration of Digital Pen&Paper into the CTDMs system (or into any other information system used by the Sponsor), there are numerous advantages:

_ simplicity: the system is intuitive, and **tracing the naturalness of the handwriting** proves to be of excellent acceptance; moreover the pen easily finds space in your pocket;

_ reliability: the battery and the internal memory allow for the **storage of about 100/200 closely written pages** without needing to recharge;

_ personalization: each module is distinguished unequivocally by the digital signature embedded in the model and **carries faithfully what written in the original document;**

_ immediacy: the updating of the trials can take place **in real time** and in general the management process accelerates;



_ integration: the sending of the data to the host computer is **immediate** and renders possible integrations with heterogeneous systems of Data Management;

_ conformity: the source documents remain on the paper and they are countersigned by the Investigator; the validation of the systems lead in universal accepted way does not represent a problem and GM is highly skilled in the management of all related documentation.

Our offer

GM Servizi has a multi-year experience in **Digital Pen&Paper technology integration in existing systems** and in **design and development of complete applications** for digital management of clinical data. This experience make us preferential actors in consulting for this innovative technology and solution, particularly in relation with clinical research.

GM offers a **global consultancy** for end-to-end solutions using Digital Pen&Paper technology with different partnership agreements.

GM can behave as:

_ Service Provider

GM can offer a complete application package inclusive of **advanced Digital Pen&Paper functionalities integrated in a Data Management system**.

_ Systems Integrator

GM can offer consulting, management and support services for **Digital Pen&Paper technology integration into pre-existing frames**.

As a system integrator, GM can also collaborate with software houses interested in Anoto technology.

_ Application Developer

GM can offer **wed based on demand applications based on Anoto functionality** for companies interested in workflow optimization thanks to Digital Pen&Paper technology.



For more information, please visit:
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