



Life Sciences
Companies

Health Agency Tracking System (HATS)

Product & Services Bundle for

Winchester's Health Agency Tracking System™



Manage all inquiries and correspondence with Regulatory Agencies

Continuous interaction with health agencies around the world is a fact of life for all Life Sciences companies. Tracking interaction and providing timely responses to queries by the health agencies falls generally within the purview of the *Regulatory Affairs* organization of a Life Sciences company.

Company Initiated Interactions -- Sometimes the interaction and correspondence is initiated by the Life Sciences company. These interactions often include submissions, letters, and requests.

Agency Initiated Interactions -- In other cases, the health agency initiates the interaction. Often the agency-initiated interaction is called an inquiry or query.

An initiated interaction could be in practically any form written or verbal. Among those forms are phone calls, e-mails, letters, meeting minutes, and formal announcements.

The ramifications and potential negative impact of not properly tracking agency-generated queries and not providing timely responses to those queries can be monumental.

A similar case can arise by not properly tracking all interactions with health agencies.

The tracking of interactions – when documented -- is generally called *Regulatory Correspondence Tracking*.

Winchester's Health Agency Tracking System, HATS™ manages time-critical information, regulatory documents, and schedules about submissions and other correspondence between the company and health agencies. HATS is the award-winning computer software system which satisfies a company's need for a Regulatory Correspondence Tracking System.

The "bundle" offered by IBM Life Sciences described in this document is meant to provide the client with the correct hardware, software, and deployment services to meet the requirements for a Regulatory Correspondence Tracking System.

The bundle is comprised of four components:

1. Protocol Manager
2. IBM Server
3. Lotus Workplace Components
4. Consulting support services

Winchester's HATS Software:

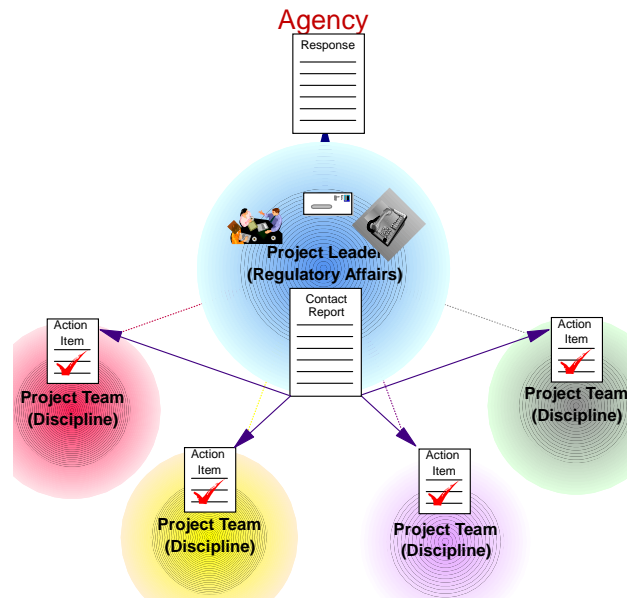
Regulatory information boundaries are disappearing as pharmaceutical and biotech companies open their networks to allow external access to internal documents. In today's regulatory environment with access via the Internet, securing these open networks, systems, and applications is essential.

Winchester's HATS software provides the highest level of access and security to on-line and on-time clinical trial information. HATS facilitates e-business models for regulatory correspondence document management by supporting a secure intranet and extranet.

HATS is a suite of integrated applications designed to assist the Regulatory Affairs Team in managing information about regulatory-sensitive documents. It is a configurable Regulatory

Correspondence Tracking Management solution. Winchester and IBM Life Sciences provide configuration services to fit HATS to your specific environment.

HATS helps you manage regulatory documents associated with all correspondence types. HATS helps the project manager develop and manage submissions and responses to queries. Its integrated applications enable users to create, review, approve, release, track, and control documents.








HATS is a Regulatory Correspondence Tracking System


Winchester's Health Agency Tracking System (HATS) is a Regulatory Correspondence Tracking System. HATS tracks all inquiries and responses made by and to health and regulatory agencies. HATS can track all regulatory-related projects in a company's facilities around the world.


Lists describing drug projects and project team members are properly maintained to allow the recordings of each inquiry or correspondence to occur simultaneously with action plans to the team responsible for that drug application, 510K submission, or other submission subject.


 **Management by Exception** -- Management by exception reporting allows the Regulatory Affairs department to manage all inquiries and correspondence around the world. The formal, written responses are appended to the resolved inquiries as a matter of record. Other reports help management decrease overall response times and recognize and eliminate bottlenecks **BEFORE** they endanger a new drug's approval.

 **It all begins with the "Contact Report"** -- Correspondence and queries usually pertain to any drug or device product that has been submitted to the health agency and can be in the form of meetings, phone calls, or written correspondence. This contact results in the creation of a "contact report" that is assigned to and monitored by the project's Regulatory Affairs team member.


 **Action Items get the right people involved** -- Quite often, Regulatory Affairs will assign one or more "action items" to other project team members to resolve the issue(s) and act as supporting documentation. Significant workflow is handled by HATS workflow and the company's e-mail system to route "action items", distribute "contact reports", and track the life-cycle of the query.

 **Multiple Responses** -- HATS has the ability to generate and distribute one or more formal Health Agency "responses" acting as the official repository. Security ensures that no documents associated with a closed "contact report" can be altered, however HATS does have the ability to "re-open" closed issues.

 **HATS Features are Practical**-- Winchester has concentrated on providing highly refined "need-to-have" features throughout the application. While the system has plenty of "nice-to-have" features, the intent of **HATS** is to provide real solutions to the real customer service and quality systems management problems faced by life sciences companies today.


 **Regulatory Correspondence Tracking System provides a single system for managing contacts with health agencies** -- HATS is a single system made up of a few functional modules alleviating the need to have multiple systems. HATS


incorporates all of the tools and components to allow Regulatory Affairs to generate Contact Reports, assign action items, record team responses, track pertinent meetings, generate Word-based correspondence, track all documents by date, time and status, as well as generate the necessary management reports.


 **Configured for specific clients** -- One of the lessons that Winchester has learned over the years is that no matter how many companies have a need, no two will have the same needs. Therefore, it should come as no surprise that Winchester designed **HATS** to be flexibly deployed. The flexibility is manifested in numerous ways throughout the system including customizable screens, parameter-driven workflows, and dynamic management reporting tools.





Unique Features of Health Agency Tracking:


 **Powerful Tools** -- Health Agency Tracking integrates regulatory correspondence management processes with the extensive functionality of a collaborative groupware application. The resulting Health Agency Tracking application delivers functionally rich, comprehensive document management capabilities to the project team.

 **Remote Operation** -- Health Agency Tracking allows remote users to participate in many functions of the system via dial-up, intranet, or extranet. Requests for actions and process notifications appear in the recipient's electronic mail box. Authorized users may enter data on site or after hours via a laptop. All changes made to documents remotely, can be replicated to the Health Agency Tracking databases, thus dramatically expanding accuracy and productivity.

 **E-Mail Freedom** -- Health Agency Tracking interfaces with all known e-mail systems. Action items and document workflow tracking make free use of the users' e-mail. However, e-mails are kept external to the Health Agency Tracking processes.

 **Ease of Use** -- An intuitive look and feel to screens makes using Health Agency Tracking simple and straightforward. Health Agency Tracking users are prompted through document development by pop-up menus and internal checks on data integrity. The Health Agency Tracking Help database provides detailed user information for the Health Agency Tracking suite of applications.


 **Connections to other systems** -- Health Agency Tracking helps the project team manage documents that are ultimately placed on other system repositories. Health Agency Tracking has been connected to many other internally-developed and vendor-supplies systems.


 **Uploading data and information** -- Previously developed correspondences and submissions may currently exist in other systems outside of Health Agency Tracking. In addition to being able to connect to other systems, documents can be uploaded into Health Agency Tracking by applying some simple scripts.





Application Security and Compliance with 21 CFR Part 11


Health Agency Tracking utilizes Winchester's ComPac GxP Application for compliance with 21 CFR Part 11. Health Agency Tracking provides the following features


 **Security** -- Health Agency Tracking utilizes the most-comprehensive security model available to ensure that all information and data is viewed, read, edited, changed, and managed only by authorized personnel.


 **Audit Trail** -- Health Agency Tracking provides a human readable audit trail, at the field level, for each document in the system. Utilizing Winchester's Snapshot technology, Health Agency Tracking tracks the original value of a field, the changed (new) value of the field and records the date, time and originator of the change.


 **Digital Signatures** -- By employing a PKI based digital certificate for identification and authentication, Protocol Manager can apply a digital signature to any electronic record in the system. Once applied, the digital signature will meet the criteria necessary for non-repudiation and identity challenges, and can be considered the legal equivalent of a hand-written signature.


 **Identity Confirmation** -- The Health Agency Tracking authentication module (ComPac GxP) meets the guidelines set forth by the FDA for subsequent saving or signing of records in both a new session and in a continuous session. During the initial authentication of a session, the identity of a user is determined by the presence of that person's "private key" and the associated password for that private key. In subsequent authentications, a separate password tied to the private key is required.

 **Access Logging** -- Access to an application can be logged using the ComPac GxP tool set. When a user enters the database, the event is captured, the termination of that session is also captured and a log is written with the length of time of each session.

 **Access Control** -- One of the challenges in a regulated environment is to produce a 21 CFR part 11 audit trail of the access and permissions changes to an application. By utilizing the access control module (ComPac GxP), a full audit trail is written showing the access changes, the previous levels and/or roles and subsequent changed levels and/or roles. Utilizing the module, it is also possible to further restrict actual access to the database and provide power users the ability to update security without giving them full "DBA" or manager permissions to the system.

 **Web Authentication** -- The web based version of the tool allows a web form to capture all changes in the audit trail and perform full authentication at the saving of a record.

 **Reason for Change** -- Many key fields within a system should require a user to enter a reason for change when updating those values. The system allows the database manager to define fields that require a reason for change.

 **Rules Based Configuration** -- By default all fields within the database are audited. The configuration module allows the database manager to define rules for auditing as well as to select certain fields for exclusion, and direct where the audit trail is to be stored (internal or external to the current database).



Ease of Use

Health Agency Tracking incorporates powerful groupware technology for collaboration and information exchange. By enabling people to access and modify the same documents, Health Agency Tracking allows team members to work independently while sharing a common database.

Health Agency Tracking has been designed with deliberate simplicity, mirroring the workflow of the clinical and regulatory affairs organizations. A consistent user interface across multiple platforms, coupled with extensive on-line help, makes Health Agency Tracking intuitively easy to learn and use. Navigation within Health Agency Tracking is very easy, using buttons and icons that automatically forward users through the appropriate workflow.

The system provides a wide range of features that simplify the workflow management of clinical trial environments.

These features include:

- Linked subsystems with bi-directional cross-referencing of clinical trial documentation
- Management of documents through appropriate states of development and approval
- Automated document control
- Consolidation of review and approval history and actions associated with the clinical trial process
- Locking upon completion of controlled records
- Automatic notification and escalation to enforce action items

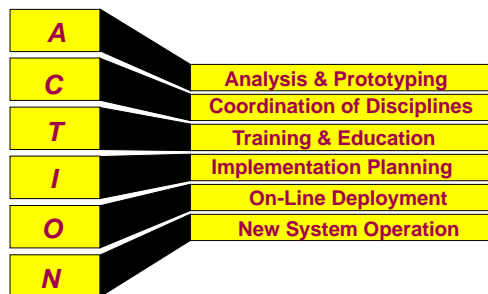
Health Agency Tracking is extremely flexible. It can easily be adapted and customized to meet specific user needs and organizational characteristics.

Health Agency Tracking employs user-controlled tables for almost every checklist-driven entry. Modification of checklists and tables are under the control of the clinical database administrator, not the IT staff.

Health Agency Tracking is scalable. It can serve a single location or an entire enterprise with global locations. Through replication, data can be synchronized across large organizations.

Health Agency Tracking has been tested with a wide variety of other applications to further extend its power to other critical functions within the organization including finance and operations. These include: graphics, video, sound, word processing, spread sheets, management reporting, and other database managers -- Oracle, DB2, SAS, and Documentum included.

ACTION Deployment Phases for Health Agency Tracking System



Computer Requirements -- Minimum

Although not required or essential, Winchester recommends:

"Computer applications that are required to be in compliance with and require validation according to FDA's 21 CFR Part 11, Electronic Records Electronic Signatures, should not be placed on the same server as other applications that need not be compliant."

Generally, most of Winchester's clients have decided to install a validated server to house all of their "Regulatory" applications.

Server:

- 800 MHz (minimum) 1.2 GHz to 2.0 GHz (recommended) Pentium Processor or equivalent
- 1 GB RAM
- If there are remote users, either a modem or Internet connection
- Network connection
- Backup facilities
- 9 GB (minimum) 60 GB (or larger recommended) available hard disk drive
- Operating System: Microsoft Windows NT®, 2000, 2003, XP, Sun Solaris and UNIX, AIX, OS/400, OS/390, Linux

Client for Authoring, Editing, Reviewing, and Approving:

- Microsoft Windows (any variety)
- Network connection
- Remote users need a modem or an Internet Connection
- Pentium 800 MHz with 128 MB or higher
- 2 GB (minimum) of Disk Space, Remote users need an additional 20 GB

Client for Reading Health Agency Tracking Documents

- Microsoft Windows (any variety)
- Network connection
- Remote users need a modem or an Internet Connection
- Pentium 300 MHz with 64 MB or higher (if using Notes)
- 120 MB of Disk Space for base install -- disk space is not required for browser-based use

Health Agency Tracking operates in a client/server environment and provides an intuitive graphical user interface (GUI). The user that only "reads documents" may choose either an Internet browser or a desktop client. Either GUI makes learning and using Health Agency Tracking simple and straightforward.



Trusted Technology Partners

Winchester's Health Agency Tracking software is IBM Lotus Workplace and IBM Lotus Domino Ready.

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