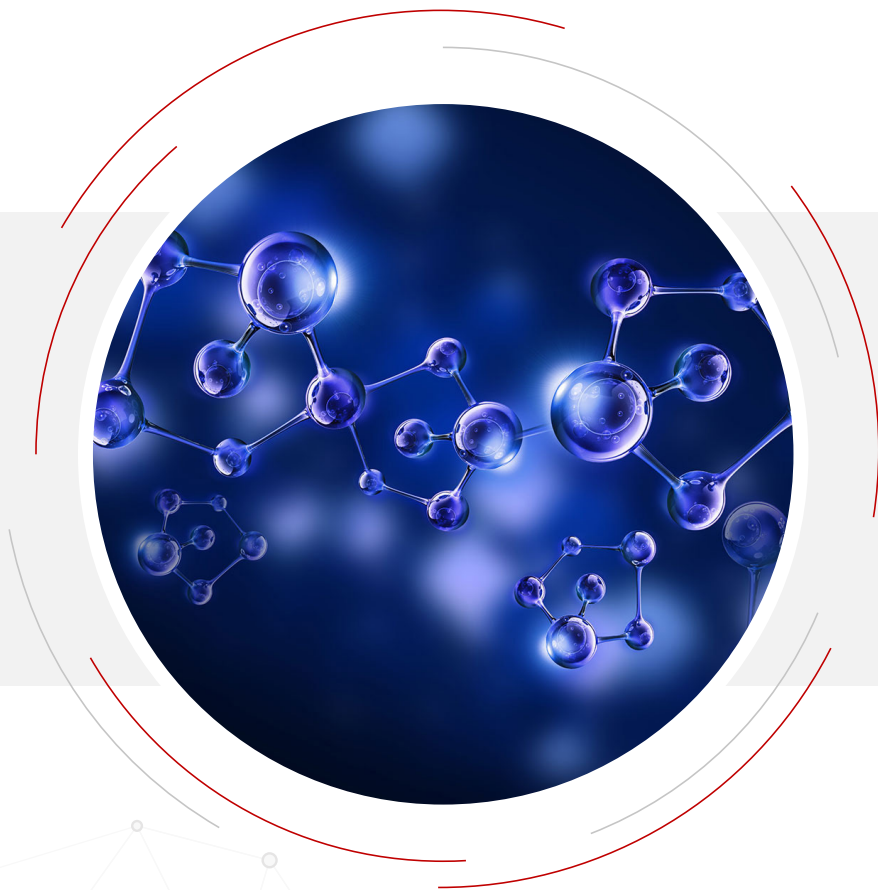


HOW TO OVERCOME THE HURDLES OF FDA FORM 1572

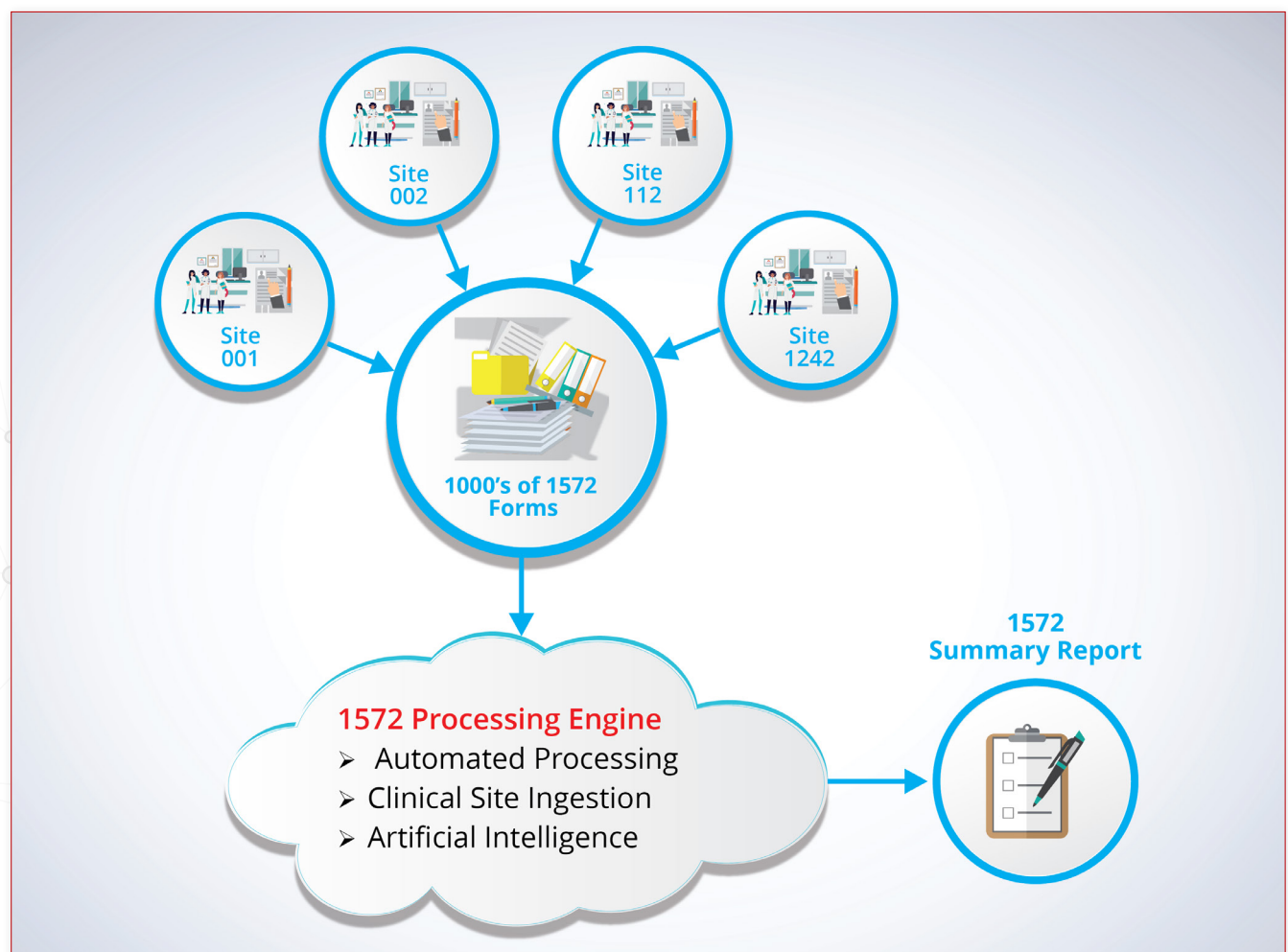


FDA Form 1572 is a mandated form that was created to provide the sponsor with relevant information about a clinical trial and to assure the U.S. Food and Drug Administration of compliance with all regulations. Yet while this simple form initially appears to be a helpful way to document a clinical trial, many organizations now recognize the process of completing the form for submission to be burdensome, time-consuming, and frustrating.

Manually combing through and combining information from hundreds of FDA 1572 forms generated across multiple sites and over a significant span of time into a summary report, clinical trial leads have reported spending hundreds of man hours dedicated to this single task.

Given the advanced technology resources available to support clinical trials, companies expect to find an easier, automated solution. Organizations are tired of losing hundreds of hours of productivity to this required task. Clinical trial leads are fatigued from manually poring through hundreds and hundreds of forms. Are you looking for an automated solution that requires no preprocessing or manual input from your team?

If these challenges are wasting your company's valuable time and resources, you'll be interested to learn about a streamlined solution changing the way clinical study reports compile information from FDA Form FDA 1572s.



UNDERSTANDING FORM FDA 1572

The U.S. Food and Drug Administration (FDA) requires the State of Investigator, Form FDA 1572 to be filled out for clinical trials that involve a new investigational drug or agent. This excludes device-related clinical trials which requires a separate but similar form. It is an agreement that is signed by the trial's investigator to provide specific information to the sponsor in order to assure all parties that the investigator will comply with any Food and Drug Administration regulations required to conduct a clinical investigation.

Due to its manual nature, there are a variety of complexities that clinical trial leads face when compiling their clinical summary reports (CSR) at the conclusion of a trial. Much of the information required for the CSR comes from Form FDA 1572, of which there may be multiple copies of for each individual site that was included in the overall clinical trial. As site investigators and sub-investigators move in and out of the trial, FDA 1572 forms must be updated accordingly, causing an increase of paperwork for clinical staff to manually review in order to compile a comprehensive CSR.

Common challenges uncovered during the report creation process mainly stem from a lack of standardization, human error, and oversight. In one example, the form may have the same primary or sub-investigator's name written inconsistently, causing the person responsible for compiling the CSR to add redundant information. Since the information recorded in these forms is collected from multiple locations over a significant span of time, there is often a lack of consistency in the format of the data. All of that information must be standardized for the final submission of the CSR, which takes significant time and effort on the part of the assigned individual.

Since there are numerous challenges that regularly occur while compiling all FDA 1572 forms, Court Square Group has created a seamless solution that allows clinical trial teams to compile clinical summary reports quickly and accurately. This software solution eradicates the need for individuals to comb through all of the raw data for the CSR, transforming a time-consuming process into a simplified audit.

THE IMPORTANCE OF FORM FDA 1572

This form is an important document to provide the sponsor with information pertaining to the investigator's qualifications as well as pertinent information about the clinical trial site. In signing this form, the investigator is making a legal commitment and agreeing to follow all relevant FDA regulations. Investigators are expected to complete the form as accurately as possible and should be warned that willfully falsifying any information on the form is a criminal offense which can result in being dismissed from the clinical trial..

WHEN MUST THE FORM FDA 1572 BE SIGNED?

Each time a new investigator is brought on to participate in an investigational new drug application, the site sponsor must receive a completed and signed form before the new investigator is allowed to participate in the clinical investigation.

Prior to submitting that signed form, the investigator should be given enough information regarding the protocol and all relevant regulations for safely conducting this clinical study. It is the investigator's responsibility to sign the form only after he or she has fully understood all the information regarding this investigation, as the investigator's signature affirms their agreement to all regulatory terms.

If there is a new site added or an investigator is replaced at an existing site, a new form must be submitted to the Food and Drug Administration within 30 days. If any site information needs to be updated, a new form must also be submitted. Many sponsors also require a new form if the primary investigator has his or her name changed, although if a sub-investigator has a name change, a note in the file explaining the change may be sufficient.

UNDERSTANDING PROBLEMATIC SECTIONS OF FORM FDA 1572

FIELD 1

Investigator's Information

This section requires the clinical investigator's full legal name and current mailing address, often a business address where the investigator can receive mail. This field should include only one investigator's name since the term "co-investigator" is not defined in the Food and Drug Administration regulations. All other clinical investigators must complete a separate form.

A common issue that is encountered in this section is the investigator's full name can sometimes be recorded in different variations, i.e. Harold Miller III, Harry Miller III, Harry Miller, etc. These instances can accidentally be recorded as different clinical investigators when they all refer to the same individual.

FIELD 6

Sub-Investigator's Information

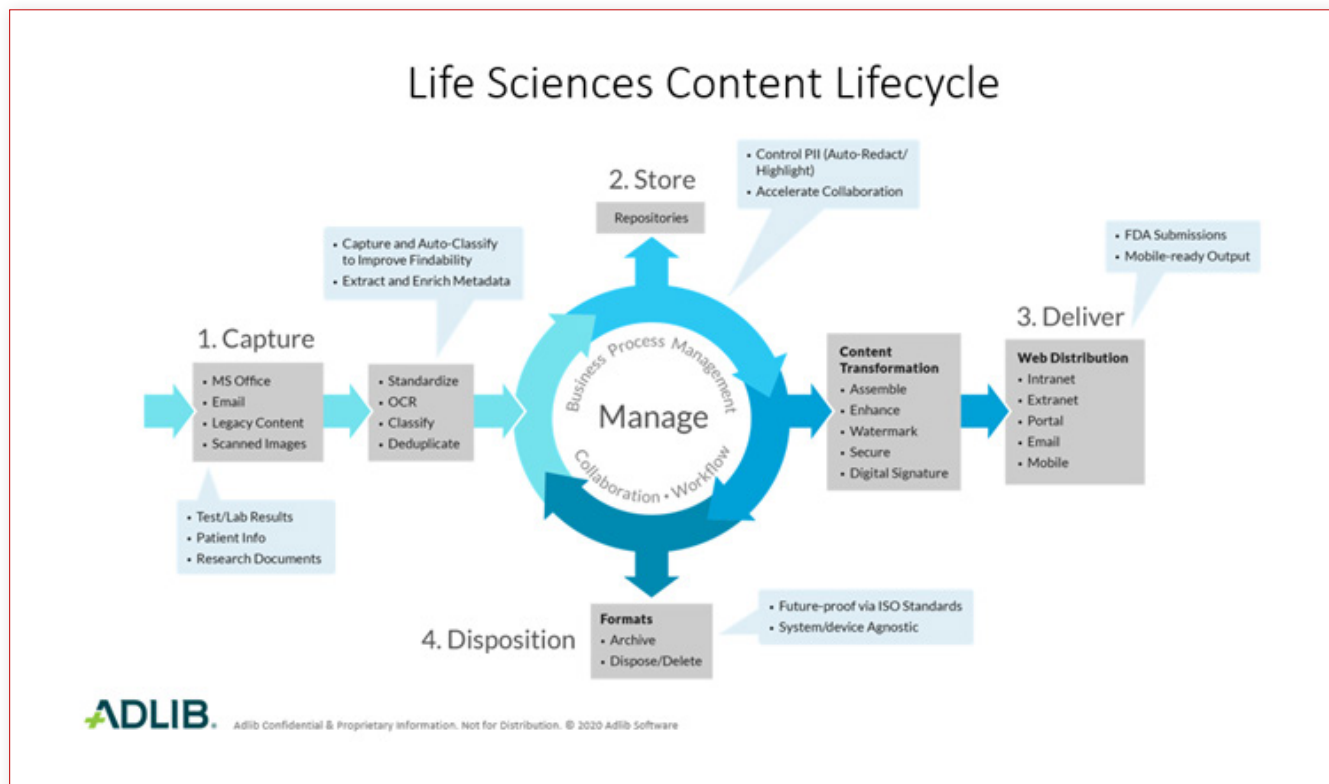
The purpose of this section is to record information pertaining to the individuals who comprise the investigative team and make a significant impact to the clinical trial and data. Individuals will qualify as a sub-investigator if they are directly involved in executing procedures required by protocol or taking part in the collection of data. Similar issues with names on the form can occur here if there is a variation of the same name or syntax errors.

COURT SQUARE GROUP STREAMLINED SOLUTION

Court Square Group utilizes Adlib. Adlib combines optical character recognition (OCR), artificial intelligence (AI), and customized coding comb through all data listed on each FDA 1572 form and pulls out all relevant data needed for the clinical summary report (CSR). Adlib is able to reconcile misspellings, understand different syntax for identical names, and identify unintelligible handwriting, and there is no preprocessing or manual effort required by the end user.

This streamlined solution iterates over all clinical sites until it has created a comprehensive CSR. This is then returned to the clinical trial lead for a final review. The built-in artificial intelligence (AI) matches all variations of names that may be identical and thus need to be merged for the final report. During this review process, the clinical trial lead can easily confirm or reject those matches with the click of a button. The clinical trial lead will then simply audit the report to ensure there is no missing information and reconcile any discrepancies in each site's section of the report.

Court Square Group's software solution is a secure and cost-effective way to ensure this important information is handled carefully throughout the review compilation process. Regardless of whether or not an organization utilizes a clinical trial management system (CTMS), this solution will significantly cut down the manpower, errors, and time it has previously taken for clinical trial leads to create a comprehensive summary report for submission.



COMMON ISSUES IDENTIFIED DURING THE REPORT AUDIT PROCESS

Perhaps one of the biggest issues that can occur at the end of a clinical trial, is the manual process that is required to complete an overall summary report. As mentioned earlier, an individual is assigned at the end of the trial to review all FDA 1572 forms for each site in order to identify and record the primary investigators and sub-investigators throughout the life of the clinical trial. Since new forms are required each time there is a change to the primary site investigator or site information, the number of forms to review per site can build up substantially. This collection process is challenging, time-consuming and prone to additional human error.

SEEING THE SOLUTION IN ACTION – A CASE STUDY

Court Square Group was approached by a clinical-stage biopharmaceutical client that was challenged by the production of their required 1572 summary reports. Working with the client Court Square Group defined a streamlined solution to create a clinical summary report for the 105 sites included in this clinical trial. There were between five to ten individual FDA 1572 documents per site, resulting in a single summary report of 67 pages under review for the final report. Rather than combing through 500 to 1,000 FDA 1572 forms to compile the finalized summary report, the clinical trial lead was able to quickly skim the deliverable summary report provided by Court Square Group for duplicates and review for any minor discrepancies. The result was a process conducted in a matter of hours rather than weeks. An additional benefit for this solution is that the summary report can be run on a regular basis as opposed to waiting until the completion of the trial.

At the end of the trial, as normal, the clinical trial lead was assigned the monumental task of compiling all information into the comprehensive clinical summary report, projected to take approximately 120-man hours over the course of a month to complete. The client had multiple clinical trials happening simultaneously, so this effort would have a big impact on the organization.

Within a few days of finalizing requirements, the client received the final CSR which was then quickly and easily reconciled by the clinical trial lead. They are now able to create and review the extensive summary report in minutes rather than months, saving significantly in dollars and time and is not suing this for all new 1572 submissions.

ABOUT COURT SQUARE GROUP

Court Square Group (CSG) is the leading provider of an Audit Ready Compliant Cloud™ (ARCC) platform for Life Science companies. The ARCC cloud platform and out-of-the-box tools provide a validated and cost-effective way to manage all digital content (EDMS/documents, voice, data, and video) in a regulated and compliant environment. At every stage of the development and manufacturing lifecycle, Court Square's cloud, collaboration and regulatory submission solutions reduce costs, complexity and risks associated with sharing, storing, and submitting information for regulatory requirements. With over 1,000+ submissions and twenty-five years' experience and a 95% client retention rate, CSG has a proven track record as one of the most cost-efficient solutions in the life science market.

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ABOUT ADLIB

Our content intelligence and automation solutions allow thousands of global customers to discover, standardize, classify, extract, and leverage clean structured data from complex unstructured documents. In doing so, our customers simplify compliance, accelerate business processes, and fuel data-driven analytics. For more information, contact us at info@adlibsoftware.com or visit adlibsoftware.com.



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FOR MORE INFORMATION

info@courtsquaregroup.com
(413) 746-0054

courtsquaregroup.com

1350 Main Street Fifth Floor
Springfield, Massachusetts 01103