Electronic Notebooks Promote Collection of Accurate and Reliable Results

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Abstract *— Electronic Notebooks favor collecting accurate and reliable results because data integrity is essential in any audit that a company may receive. It is crucial to understand that the data model has four fundamental types of integrity standards: entity integrity, referential integrity, domain integrity, and user-defined integrity. Entity integrity ensures there is no duplicate or null data. Referential integrity stipulates data storage, domain integrity guarantees the accuracy of each piece of data included in a domain, and user-defined integrity indicates the rules and restrictions established by users. Developing this change in data collection will aid in any audit, since auditors are aware that results are final and that there will be an audit trail of any changes made to the results. Companies can save time incorporating this modification, because it will speed up the testing and documentation of the tests.*

Keywords *— Data, Electronic Notebooks, Human Error, Time Reduction.*

PRESENTATION OF THE TOPIC

The pharmaceutical industry annually attends different audits, which can be internal, external, and/or unannounced. Each of these audits can focus on the product, system, quality process, manufacturing process, etc. Auditors are trained to verify the legitimacy of processes and documentation. They are very adept at finding mistakes, ambiguities in processes, and areas of opportunity within the company. That is why one of the key parts of an audit is data integrity. Data integrity is fundamental to complying with data protection regulations. Being non-compliant with the rules can make companies liable for significant penalties. In addition to penalties, the company may receive warning letters. Receiving a warning letter from an agency can be detrimental to any company. For this reason, companies should transition from paper data collection to electronic data collection. Although the paper industry is a major economic contributor, it is also one of the most significant contributors to waste, as approximately hundreds of millions of tons of paper end up in landfills [1]. In addition, the use of paper also contributes significantly to climate change and global warming due to deforestation, which also contributes to air and water pollution [2]. Also, to be considered is the financial cost each company contributes annually on paper which in return ends up as waste. The pharmaceutical industry should move to electronic data collection, especially in the laboratory area. With the implementation of electronic logbooks (ELN), the connection for equipment to transfer data directly to an electronic notebook will simplify the data collection process without human error. This type of notebook complies with the Food and Drug Administration's (FDA) 21 CFR Part 11 guidance, which specifies that the requirements for electronic signatures and records should not be distorted [3].

Situation Encountered

Laboratories that provide services to pharmaceutical and medical device companies perform a high content of weekly tests using different equipment such as balances, HPLC (high-performance liquid chromatography), ultraviolet-visible spectrophotometers, and digital density meters, among others. Each piece of equipment provides results that primarily must be transferred into a logbook. Naturally, collecting results in this way can involve human error. This is important because the integrity of the data must always maintain. Also, from the results obtained, it is concluded whether the products or reagents are

within the established parameters, which leads to a decision as to whether a product is accepted or rejected. Therefore, error minimization is a point that must be taken into consideration.

Another point affected by errors is execution time. The increase in errors adds to the run time of the tests. Creating on-line notebooks and transferring manual methods to electronic ones will help decrease both points. A major benefit that companies will have by saving the money allocated, which can be seen as a profit gained. For that ww ask the question of how beneficial it is to have electronic notebooks for time conservation and reducing human error in transcribing results?

Background and Trends

Fulfilling audit requests is of the utmost importance, which has caused many corporations to have moved their records, data and results to electronic methods, allowing them to be accessed at any time. Much research has been done on electronic notebooks, the benefits of electronic notebooks, and whether they replace paper. The article “Electronic Laboratory Notebooks Progress and Challenges in Implementation” explains how paper replacement is believed to be critical to productivity improvement. Several benefits mentioned are the ability to make traceability and searches more agile and thus foster collaboration and information sharing. This has the advantage of eliminating manual illegibility, damaged or lost data, and reducing the cost of storing and retrieving documents. Reports from Atrium Research presented in the article show that in 2011, when transferring to an electronic notebook, there was a 20% increase in productivity with respect to the processes of documenting experiments, finding information to be reused, and collaborating more efficiently [4]. Manually copying results is considered counterproductive and takes valuable time away from the work. Electronic notebooks now play a key role in early and late development and are, therefore, an integral part of the IT lifecycle. This new evolution is being seen as capable of creating and capturing workflows, as well as new data access and analysis, to aid biotechnology and pharmaceutical development to extend and support information [4].

RESEARCH MODEL

The population for this study was selected randomly; 15 analysts were chosen from the 30 analysts available to perform the analyses. Each method was performed in duplicate, and the results were analyzed. To answer the research question, an action plan strategy was created.

The project's first objective was to evaluate the test methods of the selected laboratory. This step was considered first, since the first step in the execution of any experiment is the lesson and compression of the test to be performed. Not all methods were considered because not all methods needed to be transferred to an online platform. Of the 30 methods available, segregation was made by creating a list of requirements; in this way, it would be possible to proceed with a separation between those that were considered for the project and those that were not.

In Figure 1 the form that was created for the segregation of methods; had a series of key questions to be evaluated, providing unambiguous answers. Each question was chosen to obtain beneficial information for the evaluation. The form provided a baseline of information for the more specific issues encountered in the project. It was of the utmost importance to obtain a basic understanding of the topic so that when you work on it, you can understand it from the beginning and begin to probe further.

ID	Descripción	Evaluación	Comentarios
1	¿Método se encuentra de manera electrónica?		
2	¿Cuál es el nivel de dificultad del método?		
3	¿Cuánto días para la ejecución del método?		
4	¿Cuántos son los equipos utilizados?		
5	¿Equipos tienen la habilidad de ser conectados con la interfase electrónica?		

Figure 1

Evaluation of the Methods Used in the Laboratory

ID	Instrumentos	Conexión Electrónica	Compatible con aplicación	Evaluación	Comentarios
1		☐Sí ☐No	☐Sí ☐No		
2		☐Sí ☐No	☐Sí ☐No		
3		☐Sí ☐No	☐Sí ☐No		
4		☐Sí ☐No	☐Sí ☐No		
5		☐Sí ☐No	☐Sí ☐No		

Figure 2

Evaluation of the Instruments Used in the Laboratory

Analyze Equipment

Although there are instrument questions in the methods evaluation form, this part was to be more detailed and use a deeper approach. Laboratories have a peculiarity, and that is that the use of equipment is highly probable. In former times, experiments were performed on glassware, but that had changed entirely in modern times. The number of experiments that do not use equipment is in the minority. Something very important to know is that not all equipment is made in the same way, and therefore, an analysis must be carried out on each piece of equipment used. For this, the researcher created another form like Figure 1 but more focused on the devices. The evaluation form (Figure 2) requires detailed and specific answers. Only one team per ID should be used, so that the answers obtained are descriptive of the instrument. It is recommended that the evaluation box be focused on its use; if it has a peculiarity, it should be noted in the comment box. It is important not to leave it unnoticed if it has an electronic connection and if it is compatible with the selected software.

Time Study and Error Assessment

Parra et al. explains that the time and motion study is a tool used to determine the standard times of each of the operations that make up any process and to analyze the movements that an operator performs to carry out that operation [5]. Thus, it was determined that an evaluation of the execution time should be applied to this project. Different methods are currently available to perform a time study. However, the one that would be used is comparing execution times in the execution of the same method with online templates and manual forms. Two methods, online and manual forms were used. This research only focuses on the complete work and not on steps, from when the technique is downloaded to when it is delivered for review. It is essential that the study be conducted in the same way so that the only variable measured is time. This is very important

because it is possible to confirm or reject the claim that online methods reduce the time consumed.

Human error is a topic that should always be evaluated because of the high probability of its occurrence. The type of error could be considered a group of acts exceeding an acceptance limit [5]. The evaluation of errors was measured similarly to the time study. We counted the number of errors made for each experiment in general and not for each step. Thus, only the error variable is taken into consideration. The same methods selected for the time study was evaluated here. The time study and error evaluation form (Figure 3) were used per method. At no time should the form be used for multiple processes, as it will not capture the best information and valid data for detailed analysis.

The design was structured into three parts. The first was based on general information, such as the evaluation process, the department it belongs to, the researcher's name, and the analyst's name. It was important to emphasize that the analyst must be the same in all studies. In the second part, a comparative time study was carried out. It was necessary to note the beginning of the execution until the process documentation was finished. Instruction was applied in the same way for both times. Finally, the evaluation was measured by the total amount performed in the experiment. This provided a more comprehensive approach.

Employee Survey

Obtaining input from employees, who are the ones who use and perform the work daily, was of utmost importance. Therefore, the Six Sigma voice of the customer (VOC) analysis tool was applied, which describes how to understand customer expectations and requirements to make improvements aligned with customer requirements [6]. Data collected with this tool can help support the selected process. The survey was the employee data collection instrument, so it will be in a partial way.

The results obtained in the survey (Figure 4) will help to differentiate, which is the preferred way for analysts to use daily. The decision was made to ask the same question differently to avoid adding a bias to one side over the other. One thing that the voice of the customer stipulates is not to add any bias to the consumer; this is to be avoided at any time. Therefore, each question was answered yes or no, and there was a box for them to add comments so we could know if any information was overlooked.

1. Información General	
Método:	
Nombre del Investigador:	
Nombre del Analista:	
Departamento:	
2. Estudio de Tiempo	
Tiempo en línea:	Tiempo manual:
Comienzo: Finalizo: Tiempo total toamdo:	Comienzo: Finalizo: Tiempo total toamdo:
3. Evaluación de errores	
Errores en línea:	Errores manuales:
Comienzo: Final: Tiempo total tomado:	Comienzo: Final: Tiempo total tomado:
Comentarios:	
Fecha:	

Figure 3
Time Study Form and Error Evaluation for Selected Methods

Preguntas	Sí		No
¿Prefieres el método en línea más que manual?			
¿Encuentro abrumador el método manual?			
¿Encuentro abrumador el método en línea?			
¿Sientes que tu carga de trabajo minimiza al tener métodos manuales?			
¿Sientes que tu carga de trabajo minimiza al tener métodos en línea?			
¿Te gustaría que todos los métodos se encontraran manual?			
¿Te gustaría que todos los métodos se encontraran en línea?			
¿Tienes algún comentario?			

Figure 4
Voice of Customer Survey for Employee Preference

ANALYSIS

Tools

Minitab Statistical Software is a statistical analysis tool used for data analysis. It is an interactive software used in business processing. It helps discover trends, find and predict patterns, uncover hidden relationships between variables, and create stunning visualizations to address even the most challenging challenges and opportunities [7]. It also offers extensive statistical analyses and simple graphs used in multiple professions. Examples are creating graphs with raw data, organizing various graphs, and using the wizard. This is why this program was selected. Compared to other statistical tools, the one that does not benefit the most is Minitab. The random data tool was used to choose which method was to be used for the time study. This helped us select a group of methods and equipment without bias toward any specific one.

Methods and Equipment Evaluation

Obtaining information from the methods and equipment was of utmost importance, as they contributed relevant data to the experiment. Two forms were constructed to extract valuable information from understanding electronic notebook creation. It was necessary to know if the methods could be created electronically, and it was found that out of the 27 methods, all were available electronically. It was also essential to understand their level of difficulty. The methods with a moderate level have the highest percentage, and the lowest rate is the complex level. As known, the difficulty of a method is directly proportional to the execution time. That is why the same number of complex methods had the longest execution time.

For the equipment, it was essential to emphasize that not all the teams are built in the same way or serve the same purpose; that is why it was necessary to analyze the instruments used in the executions. All equipment's were tabulated in the evaluation form created, and the questions were answered. Twenty-five percent of the instruments can be connected electronically, while the remaining seventy-five percent cannot. Of the twenty-five percent, only one instrument was incompatible with the application chosen for this experiment, while the remaining one could link to the application.

Time Study and Error Assessment

Prior to performing the time study and error assessment, the methods and analysts needed to be selected. Doing this without bias was crucial, as it is a variable that could impact the performance of the evaluation. For that reason, the random data selection tool found in Minitab was chosen. It does the job without bias. Each method was assigned a number equal to the analysts, and the results were placed in a column on the worksheet. Out of twenty-seven methods, 19, 8, and 14 were chosen. Only three methods were chosen, since together with the number of employees, it was a healthy sample of 15. The form (Figure 3) was completed for each analyst by method, and the data collected were copied into a Minitab worksheet. In the statistical study, a two-independent sample t-test was used to compare and determine if there was a statistically significant

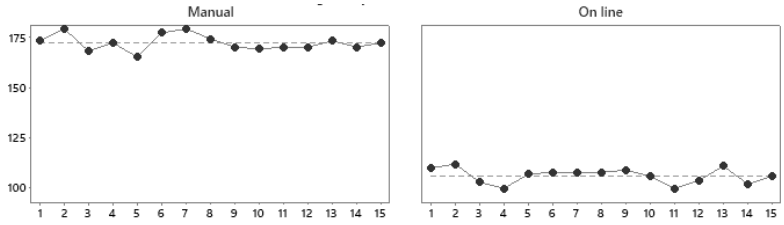

Figure 5
Line Graph for Run Time (min) per Analyst for Manual and On-line Method 19

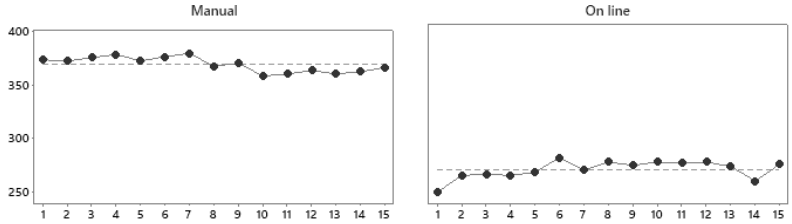

Figure 6
Line Graph for Run Time (min) per Analyst for Manual and On-line Method 8

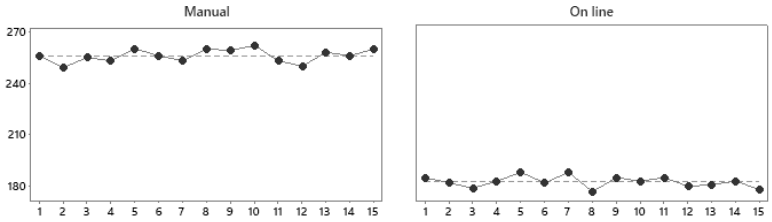

Figure 7
Line Graph for Run Time (min) per Analyst for Manual and On-line Method 14

difference in the mean. This study was performed on the three methods to compare online and manual execution.

A stipulated theory was that methods that could be documented online would be completed faster than manual. In Figure 5, Figure 6, and Figure 7, we can see the difference in time between being documented manually or online. Although outliers are found, most of the data is similar, indicating that compilation is feasible. The data dispersion for each method was also analyzed. The information it provides is that the manual execution time for the three methods increases dramatically compared to the online execution time graph. This indicates that digitized procedures greatly benefit the companies that implement them. Taifa et al. explain how cycle time reduction improves productivity in the manufacturing industry [8]. Cost reduction and meeting established objectives are directly proportional to the decrease in execution time.

Not only was the time evaluation critical, but the number of errors made in the execution was also significant. In the pharmaceutical industry, the results must be reliable and accurate, therefore failures must be kept to a minimum. Figure 8, Figure 9, and Figure 10 are line graphs for the number of errors made in the selected methods. Figures 11 and 13 show three outliers since the trend of the number of mistakes made on the digital platform was zero. There is minimal variability in the data; however, compared to the manual run, not only is the variability greater, but the number of errors was more frequent, and all these errors were

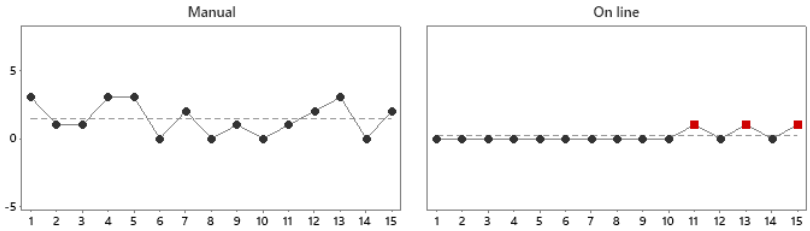

Figure 8
Line Graph for Number of Errors Made per Analyst for Manual and Online Method 19

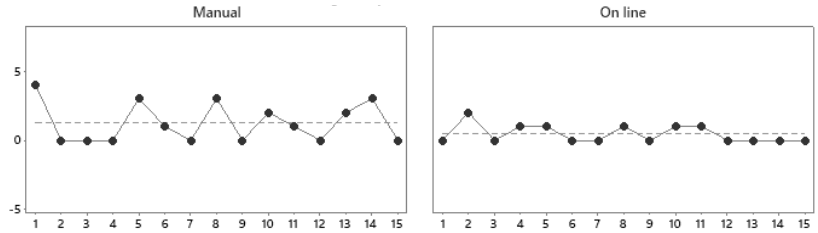

Figure 9
Line Graph for Number of Errors Made per Analyst for Manual and Online Method 8

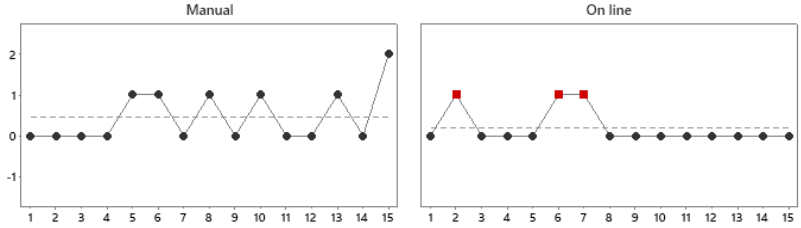

Figure 10
Line Graph for Number of Errors Made per Analyst for Manual and Online Method 14

documentation errors. Although Figure 9 shows a higher number of outliers in the online procedure, the distribution of data is more balanced when compared to the manual plot. It still has a trend of zero errors. Although the averages of the three methods do not differ much from each other, it is undoubtedly that one has a pattern of minimizing errors and speeding up performance.

Employee Survey

Obtaining input from employees should always be a priority in any job since they are the ones who carry out the day-to-day procedures. That's why the survey was arranged, with key questions to determine how each one felt. A choice was given as to whether they wanted to fill out the survey online or on paper, with the majority voting for paper. Once the survey was completed, they dropped it in a mailbox that was created for them, to make them feel comfortable. This decision was made so to not induce bias and to keep the survey completely anonymous. They were given a time of one working day to turn it in, once the 15 analysts turned in the results they reviewed. The online method came out favorably; all employees found it to be the least overwhelming method, it minimized the workload, and they would like all methods to be available in this manner. The manual was the opposite, receiving multiple comments because the methods are lengthy, and they feel that the time is doubled if done this way.

CONCLUSION

As can be seen from the research described, an evaluation of the methods and equipment must be carried out at the beginning of the study. These are the basis for understanding whether creating methods with minimum paper consumption is

possible. The above shows that all procedures can be transferred to electronic logs, but not all equipment can be connected electronically. This results in the methods not being entirely paperless since they are not mutually exclusive. The execution time of the methods and the amount of equipment used must be evaluated. The information obtained is helpful if you want to perform a time study and error evaluation. Although the data is generalized and not in detail, it is a basis for these steps.

After reviewing the data, the researcher found that having notebooks in lines helps drastically minimize human errors, which had already been established to be very important because companies must attend different internal, external, and/or unannounced audits annually. The documentation process is a key part of the quality process, and auditors are trained to verify the legitimacy of documents. Data integrity is fundamental to complying with data protection regulations. Being non-compliant with the rules can make companies liable for significant penalties. That is why the help that having the right processes in electronic platforms provides so that the employees running the experiments daily do not make human errors is very important because the workload in many companies is excessive. This was confirmed in the survey conducted. Also, time reduction was highly impacted when procedures could be collected online. These findings answer the research question: having electronic notebooks and methods online was beneficial for time conservation and reducing human error in transcribing results.

Although online notebooks are a great help, it is recommended always to have the forms and procedures to be printed out and done manually. Although having forms computerized is an advance in science, relying on them alone is a double-edged sword. If you don't have electricity or internet, you will lose work time because you cannot execute it. Also, equipment and software need maintenance, requiring time and capital to be invested to function optimally. The loss of time is not convenient for any company since deadlines and production would be highly affected. Every company is focused on making a profit rather than a loss. This topic deserves further research in the future and that this research study should be taken as a reference for future applications and methodologies to verify if electronic notebooks favor the collection of accurate and reliable results.

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