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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. 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.

Introduction

The pharmaceutical industry annually attends different audits. Auditors are trained to verify the legitimacy of processes and documentation. 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. 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 to penalties, the company may receive warning letters. For this reason, companies should transition from paper data collection to electronic data collection. With the implementation of electronic logbooks (ELN), the connection between equipment and electronic notebooks will simplify the data collection process, eliminating human error.

Background

Laboratories that provide services to pharmaceutical and medical device companies perform a high volume of weekly tests using different equipment. 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 [2]. 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. Creating on-line notebooks and transferring manual methods to electronic ones will help decrease both points.

Problem

Problem:

- How beneficial would electronic logbooks and online methods be for conserving time and reducing human error in the transcription of results?

Answer:

- Using the online notebook, errors were minimized, and time was reduced by approximately 50%.

Methodology

Laboratory Information Management System (LIMS), a platform created for a centralized database on laboratory samples. LIMS digitally records and tracks workflows, results, and instruments associated with laboratory samples. With this platform, we can directly connect to various equipment, design electronic notebooks, and product inventory. Our first step was the evaluation of the methods and equipment. Not all methods and equipment were created the same way. Some methods could be transferred to an online platform. The form for the evaluation led to the segregation of 30 methods available.

The equipment evaluation form took a deeper approach. It was created to determine whether the equipment could be connected to the interface.

The population and the method they used were randomly selected for the time and error evaluation study. The methods will be performed manually and electronically. The population were 15 analysts chosen from the 30 analysts available. Each method selected was performed in both online and manual forms.

Results and Discussion

Evaluation of methods:

All methods were evaluated and segregated by difficulty. Figure 1 shows that the category with the highest percentage was the moderate level, with 44.4%. Of the twenty-seven methods, twelve belong to this category. This indicates that, for its execution, more knowledge is required, and it involves a slightly more detailed process. In contrast to the simple level, which has 37.09% (ten of the twenty-seven), only scientific knowledge is required, and the number of steps is much smaller. With 18.5% (five of the twenty-seven), the complex level suggests that its application is much more detailed and tedious than the others. We saw how the most difficult methods are those with the longest execution time.

Analysis of equipment:

Not all teams are built the same way or serve the same purpose, which is why it was necessary to analyze the instruments used in the executions. All teams were tabulated in the evaluation form, 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 chosen application for this experiment, while the remaining ones could be linked to the application.

Employee survey:

The survey was kept completely anonymous, and participants were given a one-business-day turnaround time. The online method came out favorably, with all employees finding it to be the least overwhelming method, minimizing workload, and wishing all methods were available in this manner. The manual was the opposite, receiving many comments because many methods are lengthy, and they feel that the time is doubled if done this way.

Results and Discussion

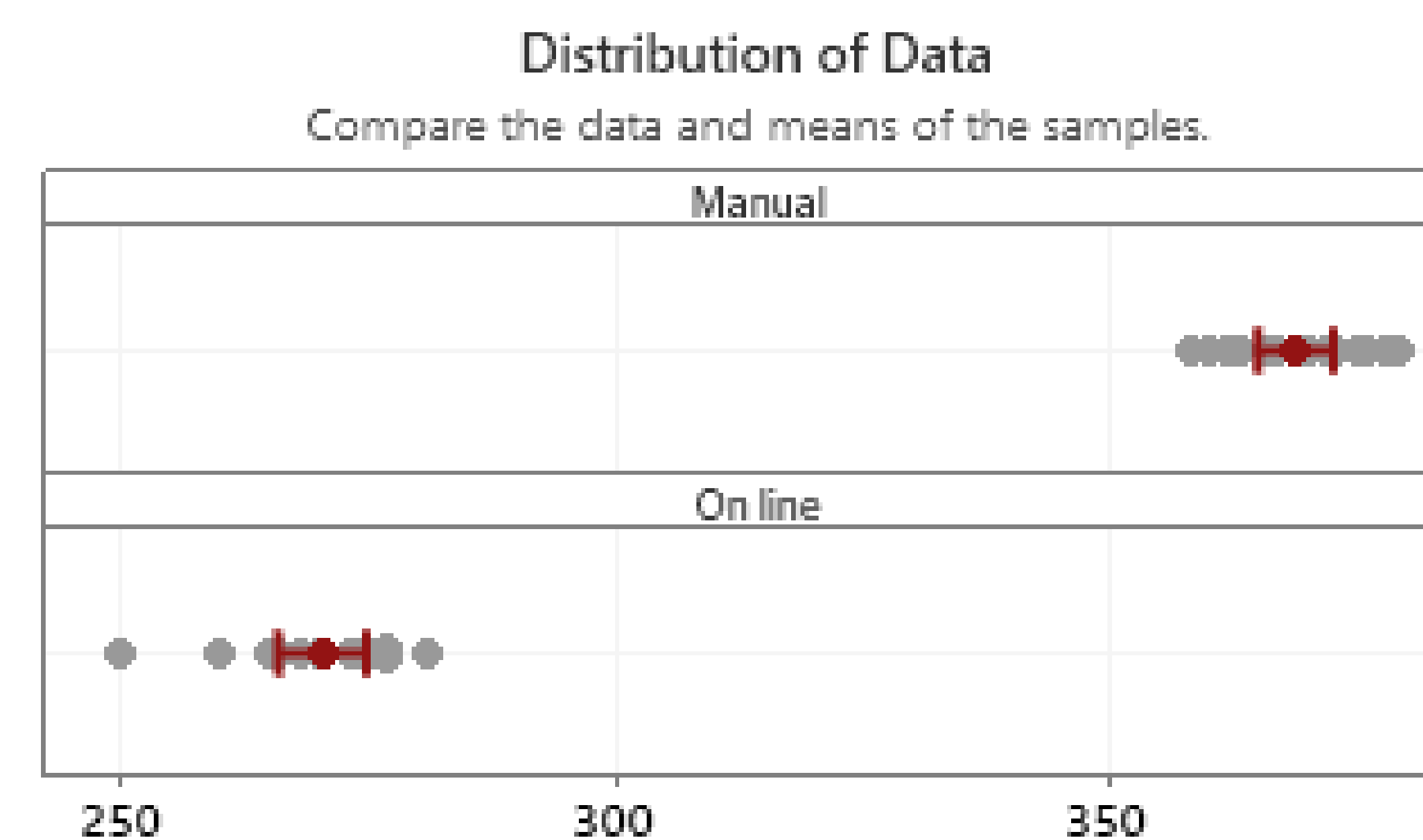


Figure 1. Scatter plot for data distribution for method 19.

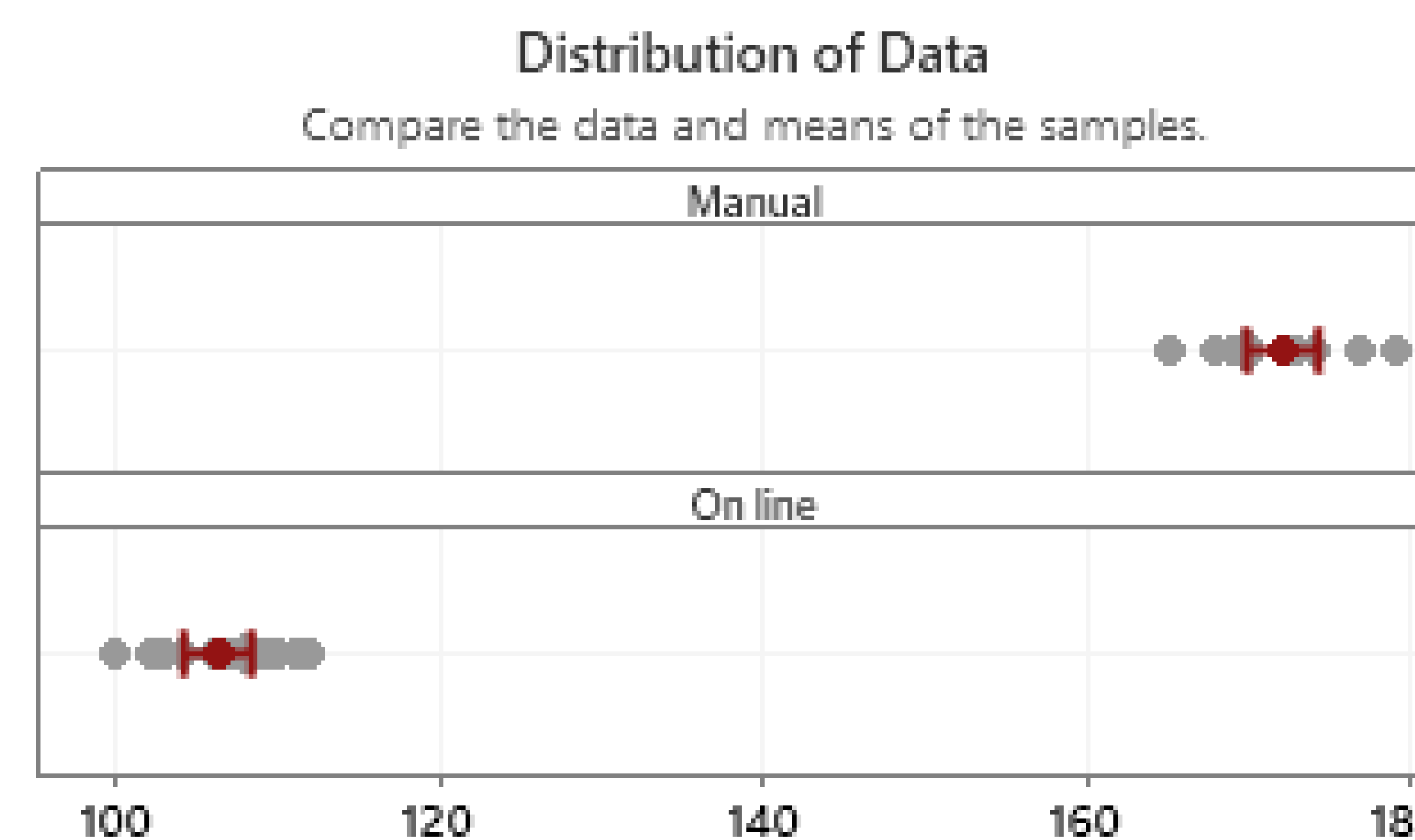


Figure 2. Scatter plot for data distribution for method 8.

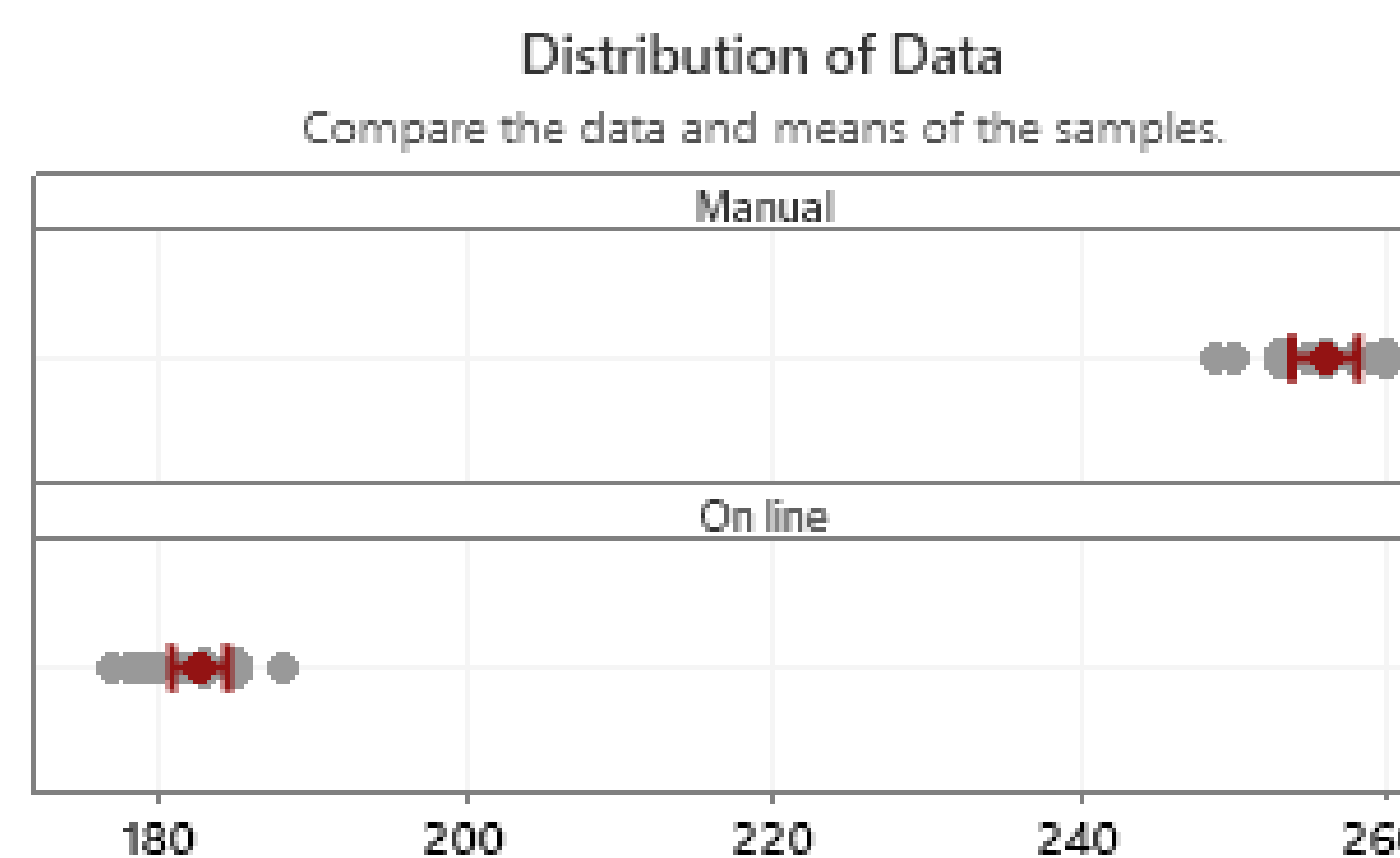


Figure 3. Scatter plot for data distribution for method 14.

Conclusions

After reviewing the data, I found that having notebooks online helps drastically minimize human errors because the workload in many companies is excessive. This was confirmed in the survey conducted. As we also saw, time reduction was highly impacted when procedures could be compiled online. These findings answer the research question: having electronic notebooks and methods online is beneficial for time conservation and reducing human error in transcribing results. Although online notebooks are helpful, it is recommended to always have the forms and procedures printed out and done manually. If there is no internet connection, work time will be lost.

Future Work

The next step is to establish a direct connection between the equipment and the interface, thereby eliminating human errors from the transcription process.

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