

Review of Warning Letters Issued to Clinical Investigators During The Years 2002 to 2011

by

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## **Introduction**

One of the main functions of the United States Food and Drug Administration (FDA) is to regulate all the activities related to development of drugs, biologics and cosmetics including veterinary products. The reason for such an oversight is to ensure safety and welfare of the human research subjects along with maintaining study integrity (Bramstedt, 2004). The FDA thus tries to maintain a thorough oversight on IND studies by conducting inspections. Any deviations found during these inspections may lead to issue of a Warning Letter to the responsible personnel or firm. A Warning Letter can be defined as a written communication received from the FDA regarding any violations that were found during their inspection. Warning Letters describe the issues that have been observed and provide a timeframe within which the company or the receiver should inform the FDA of the measures being taken to correct the violations. Failure to take proper actions may lead to further actions from FDA (Compliance Program Guidance Manual, 2008).

## **Background**

A Clinical Investigator is the main person responsible to ensure that all the activities in a clinical research site are conducted in compliance with the protocol of the study, the site is following standard operating procedures (SOPs), the safety and welfare of the subjects is maintained and all the other Good Clinical Practices (GCP) activities are being conducted properly. For the success of any study maintenance of all the above by a clinical investigator is very essential to obtain accurate and reliable results. In this course, any deviations from the protocol or standard operating procedures may lead to the chance of issuing a Warning Letter by the FDA (Compliance Program Guidance Manual, 2008).

### Who Conducts the Inspections?

The FDA inspections are conducted under Bioresearch Monitoring (BIMO) program. The main aim of BIMO program is to ensure the safety and welfare of the human subjects involved in the research, to know the accuracy of the data being collected during the study and to measure the compliance of the study with the FDA's regulations (Compliance Program Guidance Manual, 2008). These inspections are usually conducted according to guidance manuals given by the FDA. These manuals are not regulations but propose a way to conduct the inspections.

### Inspection Procedure

FDA inspections can either be announced or unannounced. The main reason of these inspections is to check the compliance of the study with the regulations, the protocol, the SOPs and other applicable regulations (Compliance Program Guidance Manual, 2008).

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Initially on arrival at the site, the FDA official issues a Form 482 (Notice of Inspection) to the site and begins to investigate the site for compliance issues. Any deviations found during the inspection are carefully noted down. After the completion of the inspection, the FDA investigator conducts an exit interview with the clinical investigator or other responsible personnel to discuss regarding the findings during the inspection. In case of any deviations, FDA Form 483 is issued. This form describes all the deviations found during the inspection. The clinical investigator responsible can answer to the deviations orally during the exit interview and/or may choose to respond in writing to the FDA (Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors, 2010).

### After the Inspection

After the completion of the inspection, the FDA investigator prepares an Establishment Inspection Report (EIR) and sends it to the appropriate FDA Center along with Form 483 (if issued). The Center then evaluates all the forms received and sends out one of the following letters to the clinical investigator (Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors, 2010):

- A General letter that states the compliance observed during the inspection.
- An Informational or Untitled Letter that states the deviations from the regulations that do not meet the threshold to issue a Warning Letter. Sometimes a written response may be requested in this case.
- A Warning Letter is issued if the deviations from regulations cross a certain threshold level of regulatory significance. These violations may lead to significant enforcement actions if not corrected voluntarily.

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- A Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) is issued if the clinical investigator has deviated from compliance or has falsified data repeatedly. This may lead to disqualification of the investigator to conduct any further IND studies.

During these inspections, there are certain serious deviations that are found more commonly which lead to Warning Letters. The examples for deviations include failure to protect the rights, safety and welfare of participants (Inspections, Compliance, Enforcement, and Criminal Investigations, 2007), failure to obtain appropriate informed consent (Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, 2006), failure to adhere to the investigational plan (Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, 2006), failure to maintain adequate case histories (Inspections, Compliance, Enforcement, and Criminal Investigations, 2012).

Receiving a Warning Letter can often be seen as a black mark in the career of a clinical investigator as it shows that there has/have been deviation(s) from the regulatory requirements in a clinical study conducted under his supervision. Also, depending on the violation, a Warning Letter shows what is lacking in the investigator's workmanship.

On the other hand, the clinical investigators may be disqualified at times. This is usually seen if the clinical investigator has been repeatedly and deliberately violating the regulations. A disqualified investigator is not eligible to either receive investigational products or conduct any research with them (Clinical Investigators - Disqualification Proceedings, 2012).

Disqualification of a Clinical Investigator affects the sponsor company in multiple ways. When a clinical investigator has been disqualified, all the clinical trials conducted under him will



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be thoroughly checked to see if there have been any errors in the data submitted by the investigator for those trials (Clinical Investigator Administrative Action- Disqualification, 2010). This includes not just the ongoing trials but also the completed trials. For example, if the investigator has participated in many clinical trials, being disqualified implies that his name can no longer be in any of the documentation. It would therefore be laborious for all the changes to be made. Hence this would definitely pose as a huge problem to the sponsor companies that have completed their studies and are ready to go into the market. Thus, a Warning Letter issued to a clinical investigator can result in many consequences that might result in delayed drug entry in to the market in some cases. Also, and more importantly, data used in support of an NDA or SNDA that were generated from a later disqualified investigator need to be removed from the efficacy analysis of the indication. If the analysis is no longer significant, the FDA may withdraw approval.

## **Purpose**

A Clinical Investigator plays a major role in the process of drug development. There have always been issues concerned to violations made by the investigator relating to many different aspects of a clinical study from enrolling patients to submitting study data to the sponsor. This project mainly aimed to know what have been the major violations that have been repeating in the past 10 years. The goal was to check all the Warning Letters that have been issued to clinical investigators during the years 2002 to 2011, i.e., a span of 10 years, to know the frequency of violations being made and see if there has been any trend in the repetition of errors occurring with respect to clinical investigators.

### **Research Question:**

Is there any trend in the violations occurring due to clinical investigators from the years 2002 to 2011 which have been leading to issue of Warning Letters?

### **Secondary Questions:**

Which is the specific violation with the highest number of Warning Letters issued?

What are the other common areas where clinical investigators tend to violate the regulations?

What is the frequency of these errors?

## **Methodology**

To answer the proposed questions, all the Warning Letters issued to clinical investigators during the years 2002 to 2011 were studied from the FDA Warning Letters index website. These letters were further classified into different groups depending on the violations for which the letters were issued. Groups were added as found during the research process. Also, the frequency of these violations was tracked along with different types of violations being made.

All the Warning Letters obtained were classified by two methods. The first method (Table 1) shows the classification of the Warning Letters based on the year of issue and the second method (Table 2) shows the classification of the data based on year of issue and the violation made. All the data thus obtained were analyzed to see the most frequent violation repeated and if there has been any trend in the repetition of these errors by the clinical investigators during the years 2002-2011. Then, the number of inspections conducted per year was collected (Table 3). Finally, the Warning Letters per year was divided by the number of inspections per year times 100 to check if there is any relation between the inspection type and if there were any significant trends.

## Results

All the Warning Letters issued to clinical investigators during the years 2002-2011 were collected and classified based on the year of issue and violations.

### Number of Warning Letters to Clinical Investigators per year during 2002-2011

The total number of Warning Letters issued to Clinical Investigators during the years 2002-2011 was 216. These Warning Letters were divided based on the year of issue to generate the number of letters issued per year. See Table 1.

Year	Number of Warning Letters
2002	19
2003	20
2004	31
2005	28
2006	23
2007	17
2008	25
2009	26
2010	13
2011	14

Table 1. Number of Warning Letters issued to Clinical Investigators. See Appendix for reference for each of these letters.

### Trend of Warning Letters during the term 2002-2011

To know the trend of Warning Letters issued to Clinical Investigators during the period of 2002-2011, a graph was drawn using the data from the Table 1.

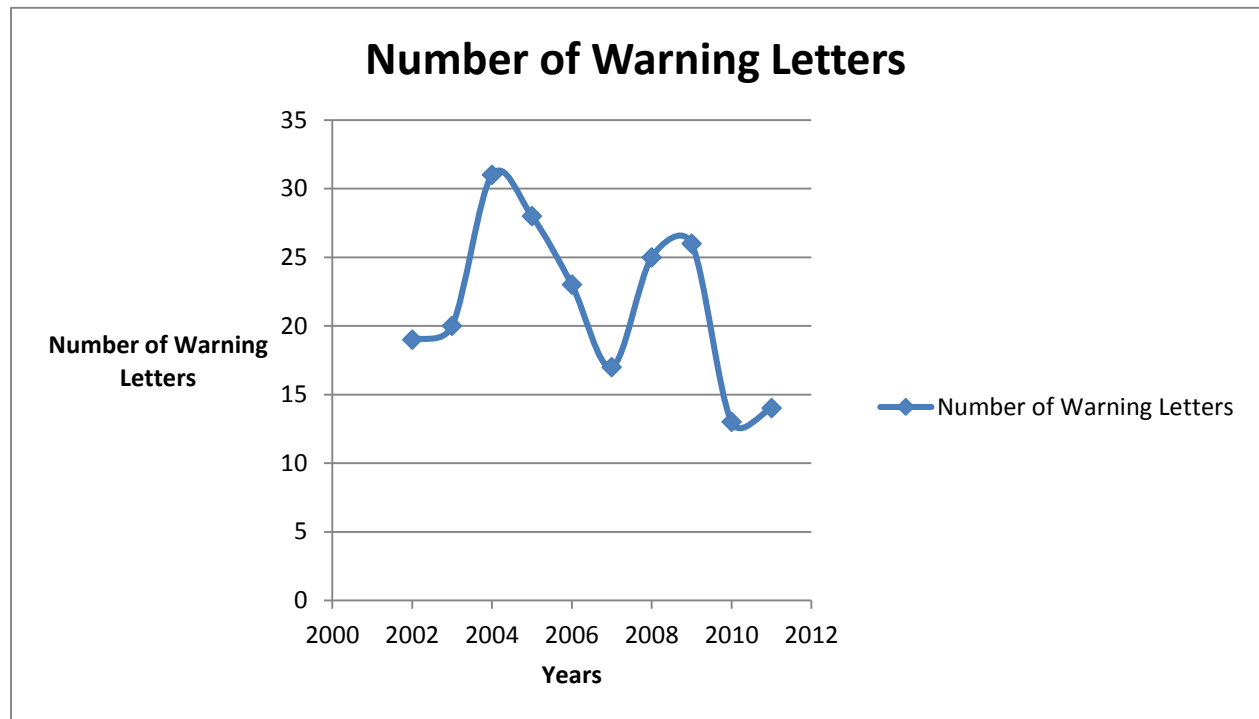


Figure 1. Number of Warning Letters issued to Clinical Investigators per year.

Statistical Analysis. Slope of the graph: -0.81212; p-value: 0.239859 (not significant)

Classification of Warning Letters based on year of issue and violations (Table 2):

The groups into which the Warning Letters have been divided were named according to the violations made and the corresponding CFR regulation number.

The Warning Letters have been divided into the following 22 groups:

1. Failure to protect the rights, safety, and welfare of the subjects under your care  
[21 CFR 312.60]
2. Failure to conduct study according to investigational plan and conditions imposed  
by IRB [21 CFR 812.110(b)], [21 CFR 312.60].

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3. Failure to ensure adequate monitoring of the investigation [21 CFR 812.25, 812.43(d), and 812.46] [21 CFR 312.60].
4. Failure to prepare and submit complete, accurate, and timely reports to the sponsor and IRB [21 CFR 812.150(a) (1)], [21 CFR 812.150(a) (2), 812.150(a) (3)] & [21 CFR § 812.150(a) (4)].
5. Failure to submit application (IND/IDE) to FDA & obtain FDA approval before beginning the investigation. [21 CFR 312.20] [21 CFR 812.40, 812.42, 812.110(a)].
6. Failure to establish all elements of and adequately document informed consent. [21 CFR 812.100].
7. Failure to maintain accurate, complete, and current records relating to documents evidencing informed consent. [21 CFR 812.140(a) (3) (i)].
8. Failure to obtain signed agreement from investigators [21 CFR 312.53(c) (1)].
9. Failure to ship the investigational drug to investigators not participating in the investigation. [21 CFR 312.53(b)].
10. Failure to obtain informed consent in accordance with the provisions of 21 CFR Part 50.20 and 812.100. [21 CFR 312.53(b)]
11. Failure to maintain records of receipt, use or disposition of the investigational product (drug/device) [21 CFR 312.62(a)] [21 CFR 812.140(b)(2)]
12. Errors in CRFs [21 CFR 312.62(b)].
13. Failure to conduct the clinical study in accordance with the approved protocol [21 CFR 312.60]

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14. Failure to maintain adequate, complete, and current records relating to the investigator's participation in an investigation, including records of each subject's case history. [21 CFR 812.140(a)], [21 CFR 312.62(b)].
15. Failure to obtain a list of the names of the sub-investigators who will be assisting the investigator in the conduct of the investigation. [21 CFR § 312.53(c) (1) (viii)].
16. Failure to ensure that an IRB is responsible for initial and continuing review of the study by failing to provide the IRB with information the IRB specifically required to be submitted. [21 CFR 312.66]
17. Failure to obtain informed consent [21 CFR Part 50.20] and [21 CFR 812.100]
18. Failure to retain records for the requisite time period [21 CFR 312.57(c)] & [21 CFR 312.62(c)].
19. Submission of false information to the Sponsor [21 CFR 312.70(a)]
20. Implanted devices that did not have an FDA-approved IDE under 520(g) of the Act or an FDA PMA under 515 of the Act and were consequently adulterated devices under section 501(f)(1)(B) of the Act
21. Failure to prepare and submit a complete and accurate final report. [21 CFR § 812.150(a) (6)].
22. Failure to promptly report to the IRB all changes in the research activity [21 CFR 312.66].

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<b>Violation Type</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>
1	3	3	5	13	4	3	2	2	4	3
2	14	13	20	26	19	16	20	25	11	13
3	4	3	3	2	3	3	5	7	3	7
4	5	7	10	11	9	6	9	3	1	2
5	1	3	3	3	5	1	3			
6	3	5	8	6	5	1	3	1		
7	2		4	3			3			
8	1	1	1	1			3	2	1	
9			1		1	1				
10	3	7	3	6	9	3	12	8	5	3
11	8	7	5	10	6	5	11	10	4	3
12							1			
13	3	2	1	3		1	3			
14	14	9	17	14	13	12	18	15	7	7
15	1						1	1		
16		2	5			2	4	4		2
17	2	5	7	3	4	3	4	3		1
18	2	1		1	1		2	2	4	1
19	3			1						
20		2	2	1						



<b>Violation Type</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>
21				1						
22	2				1		1	2	6	1

Table 2: Classification of Warning Letters issued to Clinical Investigators based on year of issue and violations made. See text for explanation of violation type.

Frequency of repetition of top five violations

The five most frequent violations were plotted on a graph to see the repetition of these violations during the years 2002-2011 (Figure 2). The data from Table 2 were used to draw this graph. This graph helps in estimating the trend of repetition of the violations.

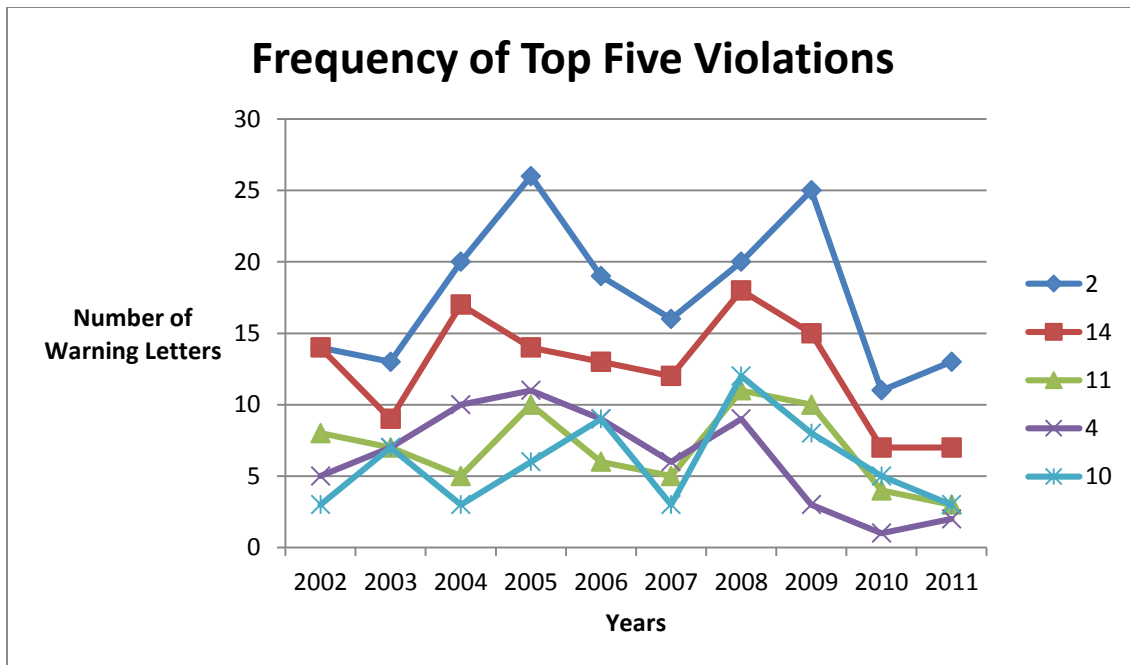


Figure 2: Frequency of Repetition of Top Five Violations. Graphical representation of the data from Table 2. In this, X-axis denotes the time in years from 2002-2011 and Y-axis denotes the number of Warning Letters. The lines indicate the violation number as described in the text.

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### Total Number of Inspections

The total number of inspections conducted during the years 2002-2011 is collected and presented in the Table 3 and Figure 3 (CDER 2002 Report to the Nation) (Office of Scientific Investigations Metrics, 2013).

Year	Number of Inspections
2002	487
2003	745
2004	721
2005	672
2006	654
2007	671
2008	701
2009	839
2010	809
2011	784

Table 3: Total number of Inspections conducted during the years 2002-2011.

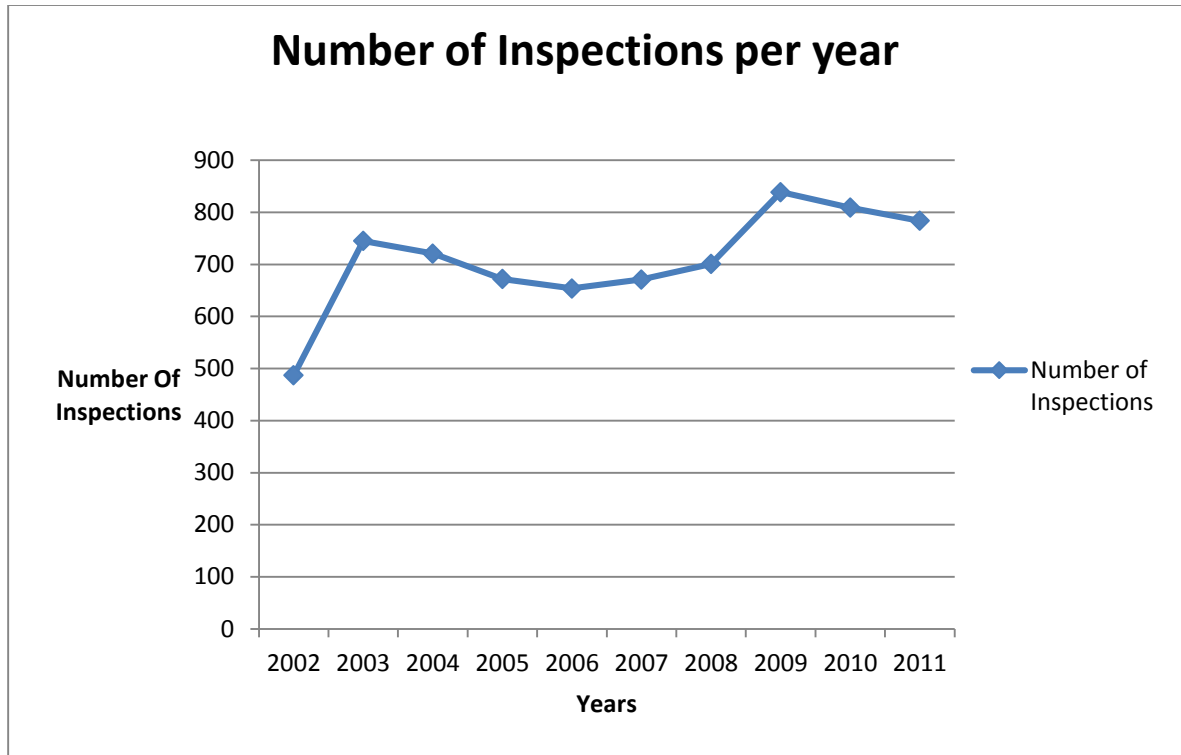


Figure 3. Number of Inspections per year. Graphical representation of the data from Table 3. In this, X-axis denotes the time in years from 2002-2011 and Y-axis denotes the number of Clinical Inspections.

For further evaluation, the number of Warning Letters issued is divided by the number of inspections per year times 100 (Figure 4).

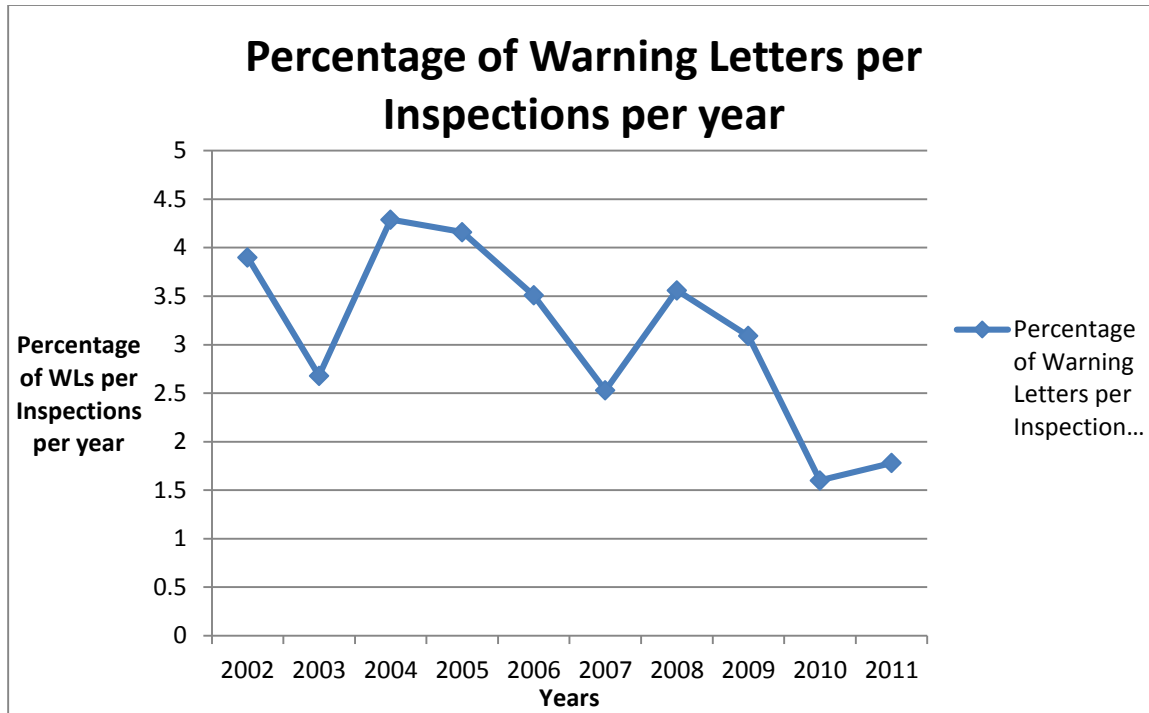


Figure 4. Percentage of Warning Letters per 100 Inspections per year. In this, X-axis denotes the time in years from 2002-2011 and Y-axis denotes the number of Warning Letters per inspection per year times 100.

Statistical Analysis: Slope of the graph: -0.2147; p-value: 1.43827 (not significant)

## Discussion

The total number of Warning Letters issued to Clinical Investigators during the term 2002-2011 was 216. These letters have been issued to investigators depending upon different violations made by them. Reviewing all these Warning Letters issued for the 10-year period from 2002 to 2011 depicts the way in which the number varied among these years. Figure 2 shows the trend during these ten years. The frequency graph shows the frequency of repetition of violations. Also it helps to know the most common violations made by Clinical Investigators.

Table 1 depicts the trend of increase and decrease in the number of Warning Letters issued to Clinical Investigators. This table shows how the numbers increased during 2004-2005 and then decreased and again increased during 2008-2009. The highest number of Warning Letters issued to Clinical Investigators in a year during the term 2002-2011 is 31 in the year 2004. The lowest number of Warning Letters issued to Clinical Investigators in a year during the term 2002-2011 is 13 in the year 2010.

Figure 1 indicates the trend of number of Warning Letters addressed to Clinical Investigators. It can be described as a double parabola with the highest point at 2004 and the lowest point at 2010. The significance of the slope was tested and was found to be not statistically significant.

Table 2 indicates the violations that have been observed in the Warning Letters. This table depicts the frequency of violations during the term 2002-2011. This data is used to know the most frequent violations and the least frequent violations committed by Clinical Investigators during the term 2002-2011.

Using the data from the Table 2, the five most frequent violations made were:

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2. Failure to conduct study according to investigational plan and conditions imposed by IRB [21 CFR 812.110(b)], [21 CFR 312.60]. (177 Warning Letters)
14. Failure to maintain adequate, complete, and current records relating to the investigator's participation in an investigation, including records of each subject's case history. (21 CFR 812.140(a)), [21 CFR 312.62(b)]. (126 Warning Letters)
11. Failure to maintain records of receipt, use or disposition of the investigational product (drug/device) [21 CFR 312.62(a)] (21 CFR 812.140(b) (2)). (69 Warning Letters)
4. Failure to prepare and submit complete, accurate, and timely reports to the sponsor and IRB (21 CFR 812.150(a) (1), [21 CFR 812.150(a) (2)], 812.150(a) (3)) & [21 CFR § 812.150(a) (4)]. (63 Warning Letters)
10. Failure to obtain informed consent in accordance with the provisions of 21 CFR Part 50.20 and 812.100. [21 CFR 312.60] (59 Warning Letters)

Of all the violations mentioned above, the most frequently repeated violation is “Failure to conduct study according to investigational plan and conditions imposed by IRB [21 CFR 812.110(b)], [21 CFR 312.60]” with 177 Warning Letters issued while the least frequently repeated violations are “Errors in CRFs [21 CFR 312.62(b)]” and “Failure to prepare and submit a complete and accurate final report. [21 CFR § 812.150(a) (6)]” with 1 Warning Letter issued for each.

Figure 2 shows the variations in the numbers of violations repeated and show how the frequency of violations varied from one another during the last ten years. There is no trend

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observed among the violations. The shape of the curve of the most common violation, “Failure to conduct study according to investigational plan and conditions imposed by IRB [21 CFR 812.110(b)], [21 CFR 312.60]”, tends to influence the shape of the curve for total number of violations due to consistent high number of violations found each year. The second curve represents the violation, “Failure to maintain adequate, complete, and current records relating to the investigator’s participation in an investigation, including records of each subject’s case history. (21 CFR 812.140(a), [21 CFR 312.62(b),]” follows with not much variation. The next three violations, “Failure to maintain records of receipt, use or disposition of the investigational product (drug/device) [21 CFR 312.62(a)] (21 CFR 812.140(b) (2))”, “Failure to prepare and submit complete, accurate, and timely reports to the sponsor and IRB (21 CFR 812.150(a) (1), [21 CFR 812.150(a) (2)], 812.150(a) (3)) & [21 CFR § 812.150(a) (4)]” and “Failure to obtain informed consent in accordance with the provisions of 21 CFR Part 50.20 and 812.100. [21 CFR 312.60],” vary little from each other or from year to year.

Thus, it is implied from all the above discussion that there is no significant trend observed with the number of Warning Letters issued to Clinical Investigators during the term 2002-2011.

The number of Warning Letters trend was compared to the number of Clinical Investigator Inspections conducted by the FDA (Office of Scientific Investigations, 2013). Table 3 shows the number of inspections conducted per year from 2002-2011. Figure 3 is a graphical representation of the data from Table 3. For further evaluations, the numbers of Warning Letters issued per inspections conducted per year times 100 during the 10-year period were studied, the results are shown in Figure 4. As the slope is not flat for Figure 4, it was tested and found to be

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not statistically significant. Also, Figure 4 shows that the number of Warning Letters issued per inspections per year was gradually decreasing.



## **Conclusion**

This project showed the number of Warning Letters issued to Clinical Investigators varied in the last ten years (2002-2011). The most common violation is the failure to conduct study according to investigational plan and conditions imposed by IRB, which can be reduced by adhering to the mandated requirements and giving importance to minor details of a protocol.

With respect to the trend of the number of Warning Letters issued, it can be inferred from all the data collected and presented that the number or type of Warning Letters does not show any significant trend. When the number of violations was examined by the number of inspections conducted, it was found that there is no statistically significant relation between them.

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