

# Comparison of Age, Duration in Clinical Trial and Country of Origin

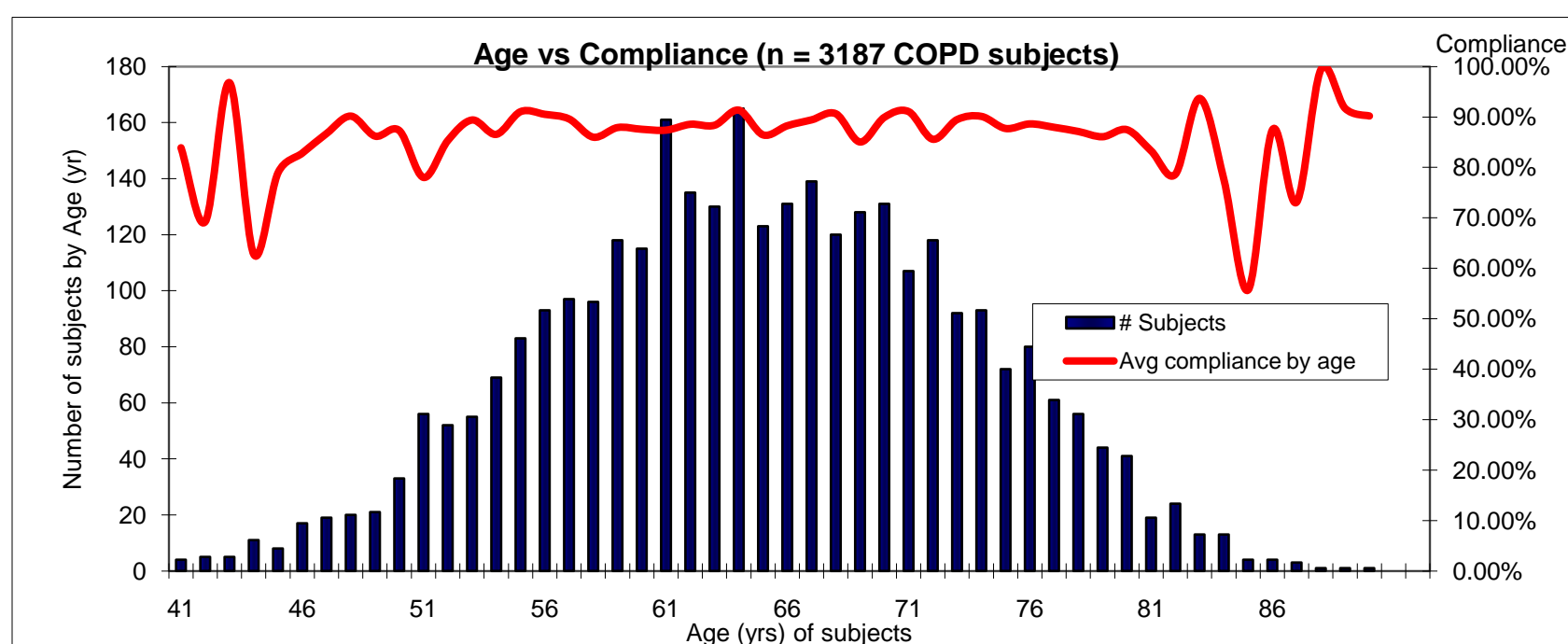
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## Background

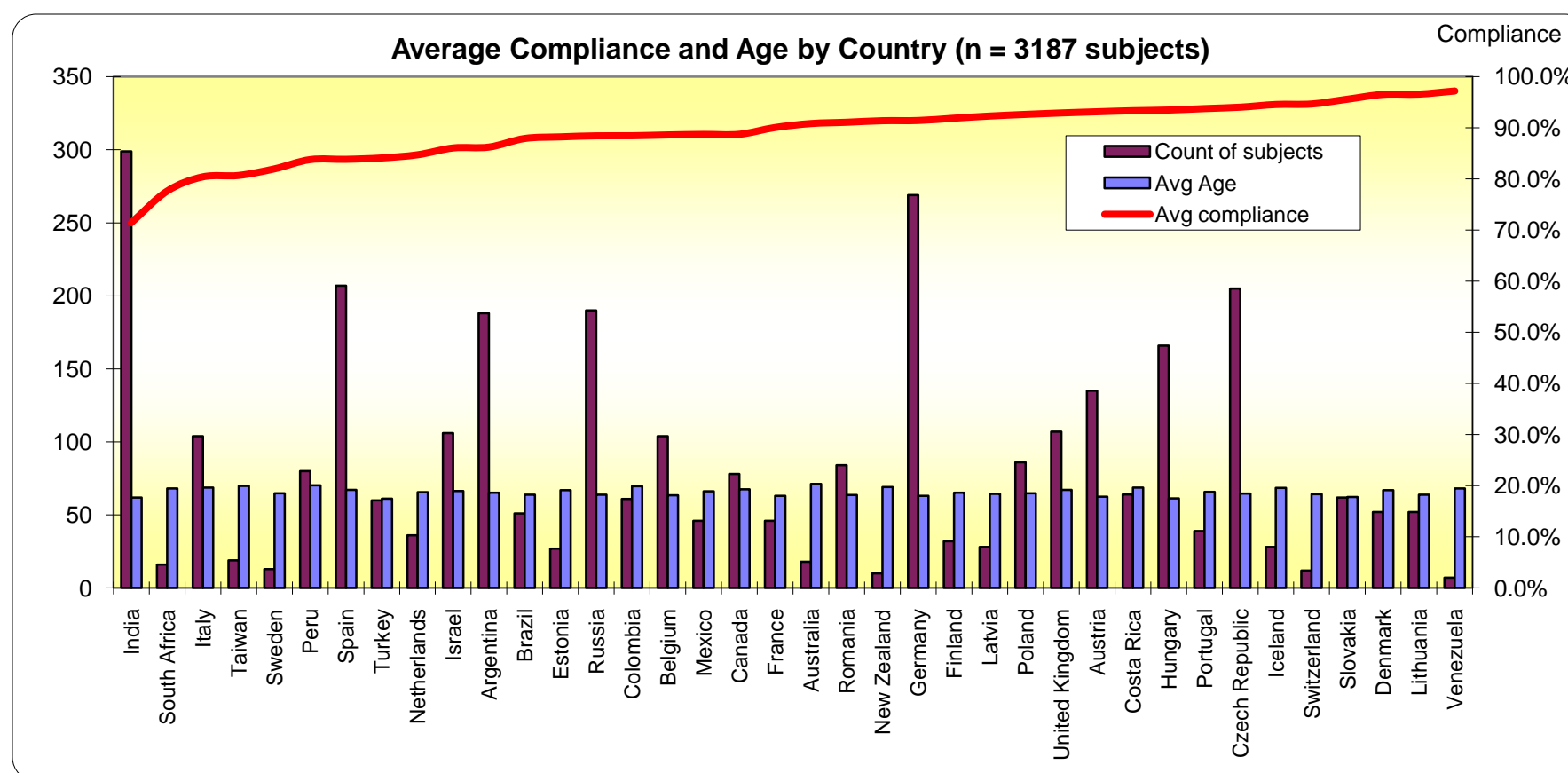
There has been a perception that either the ability or willingness to use electronic diaries may be hindered by several factors including age or disease state. It is often thought that subjects living in less developed countries may not have the level of computer experience or education to complete diaries. The duration of the study may also affect the overall performance of individual subjects to complete their daily diaries.

## Objectives

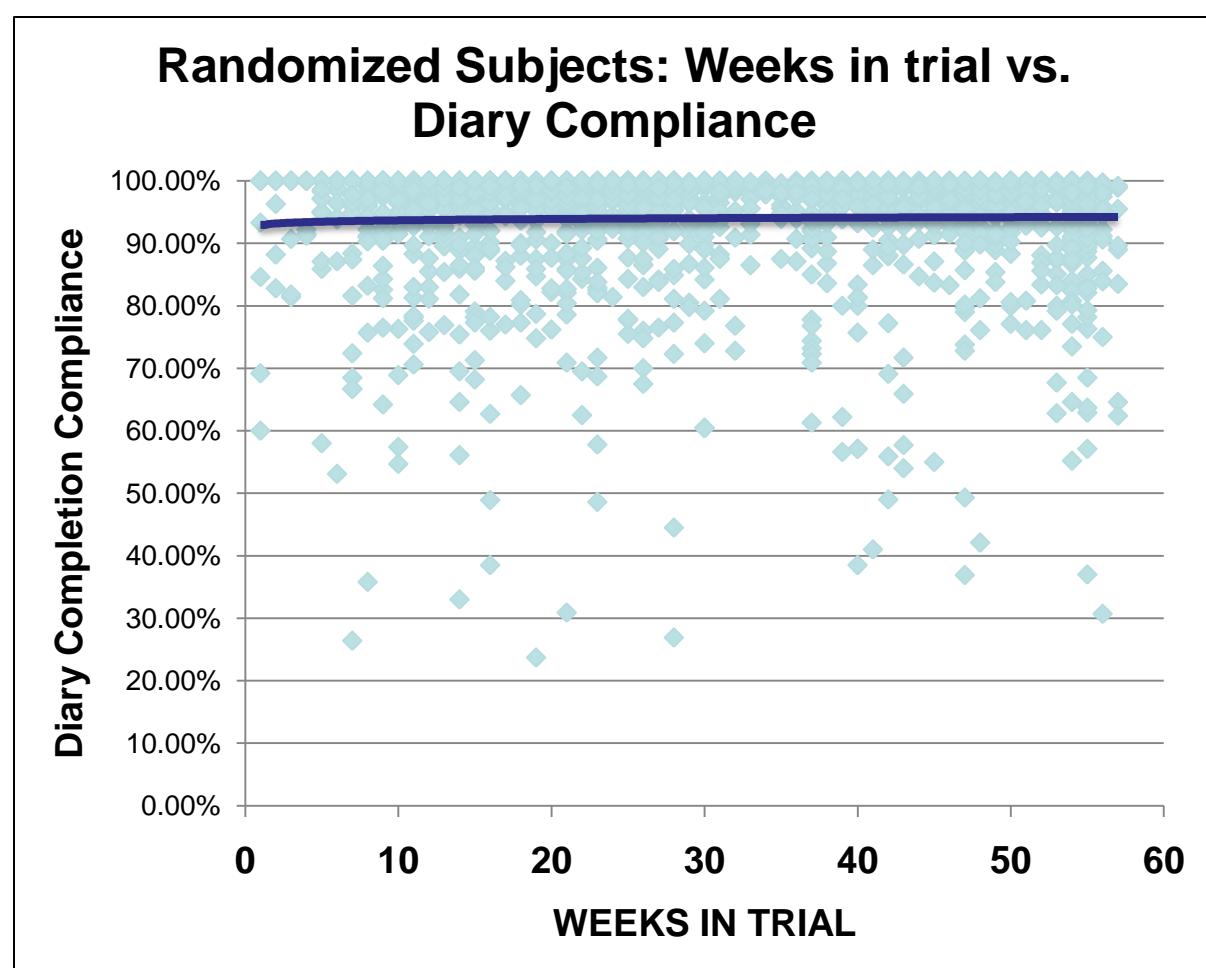
Determine if the compliance (% of expected diaries completed) is impacted by age, duration of trial participation or country of origin.



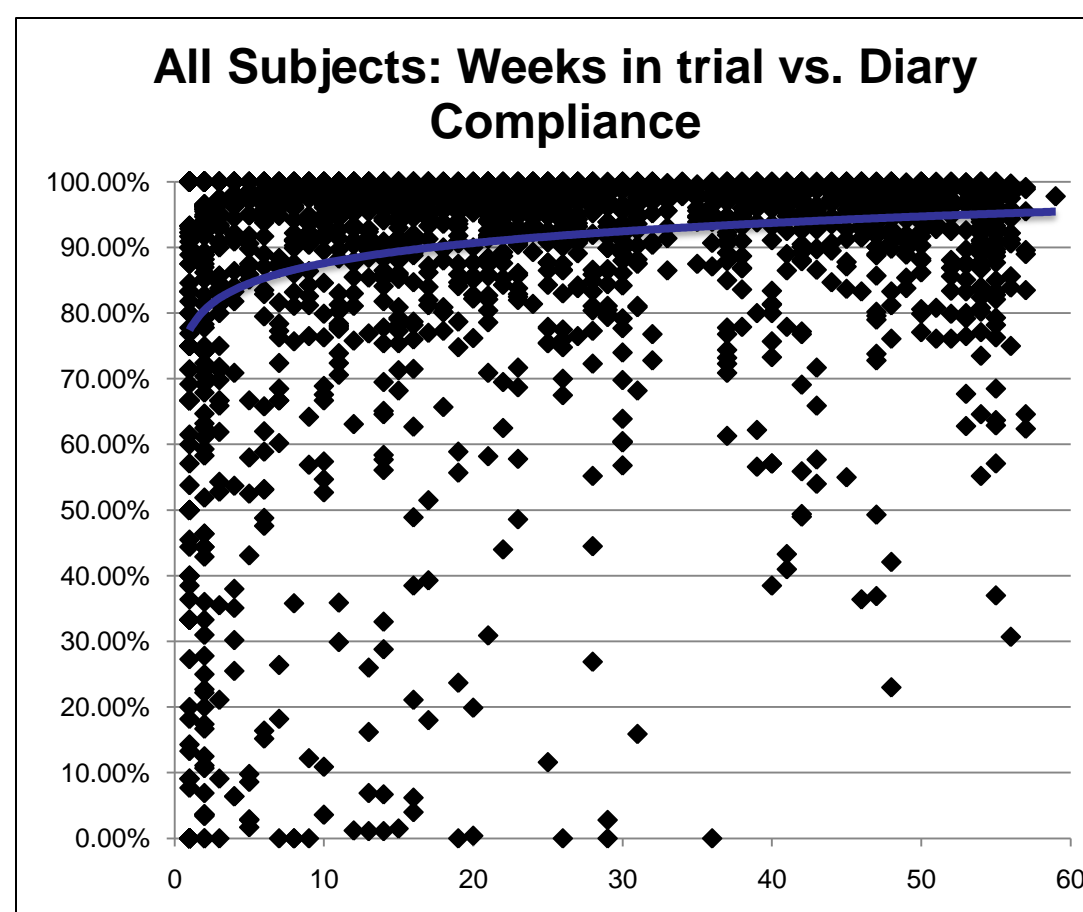
Graph 1: Number of subjects and percentage compliance by age for all subjects.



Graph 2: Subjects and percentage compliance by country for all subjects.



Graph 3: Plot of number of weeks in trial vs. percentage compliance for randomized subjects.



Graph 4: Plot of duration in trial vs. percentage diary compliance for all subjects.

## Research Design

Data from 3187 COPD subjects (aged from 41 to 92 yrs) enrolled in a clinical trial of a 52-week treatment across 39 countries was analyzed by statistical methods to determine if any of the variables correlated with the subject's ability and willingness to complete their daily diaries.

## Results

There was no significant correlation between age, country of origin and compliance. There is a small increase in compliance the longer subjects participate in the clinical trial. However, among the subjects who are currently in the treatment phase or completed the treatment phase there is no change in compliance. The overall diary compliance is 90.6% with nearly 1 Million diaries completed.

## Conclusions

This analysis of the study meta-data is further proof that subjects can and are willing to complete daily diaries electronically regardless of their age or country of origin and that the duration in the trial is not a burden that has significantly impacted their ability to complete their diaries.