The objective, methods, results and conclusions of this study as presented on this poster do not deviate in content or substance from the abstract originally submitted.

**METHODS**

We focused on the following 2 disease areas: Depression and Type 2 Diabetes Mellitus

- **Depression studies** had an average of 12.9 criteria per protocol, including an average of 20 tests per protocol

- **Diabetes studies** had an average of 24.5 tests per protocol

**RESULTS**

As we identified similarities between time clauses, a natural categorization emerged. Each time clause organically fell into one of three categories: 1) those in which the test-value pair was required to occur at the time of screening; 2) those in which the pair required to occur anytime prior to screening; and 3) those that required to happen within a different specific time period ("other").

We categorized all 1,011 time clauses regardless of the associated test-value pair and found that more than half of time clauses required the criteria be met at the time of screening (Figure 2).

CONCLUSIONS

Although there is a high percentage of similar test across studies within a given disease area, the level of similarity decreases significantly as the test-value pair components are considered.

In both disease areas similarities decreased with more restrictive criteria clauses indicating variability and/or disagreement regarding the most appropriate value and time clauses.

**REFERENCES**


