

```
proc univariate data=adpd ;
by trt01pn trt01p paramcd param;
var aval;
output out=out;
run;
```

AGE	AGE2	SEX	RACE
60	years	F	2
67	years	M	1
67	years	M	1
67	years	F	2
68	years	M	1
68	years	M	1
68	years	F	2
68	years	M	1
68	years	F	2
68	years	F	2

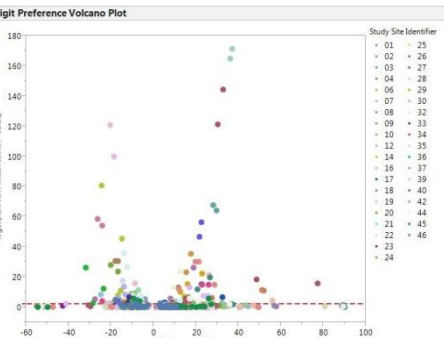
DEMOGRAPHIC		DCM - DCMST	
DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)
DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)	DATE OF BIRTH (YYYYMMDD)

```
proc freq data=test;
tables race*trtan/out=test1;
run;
```

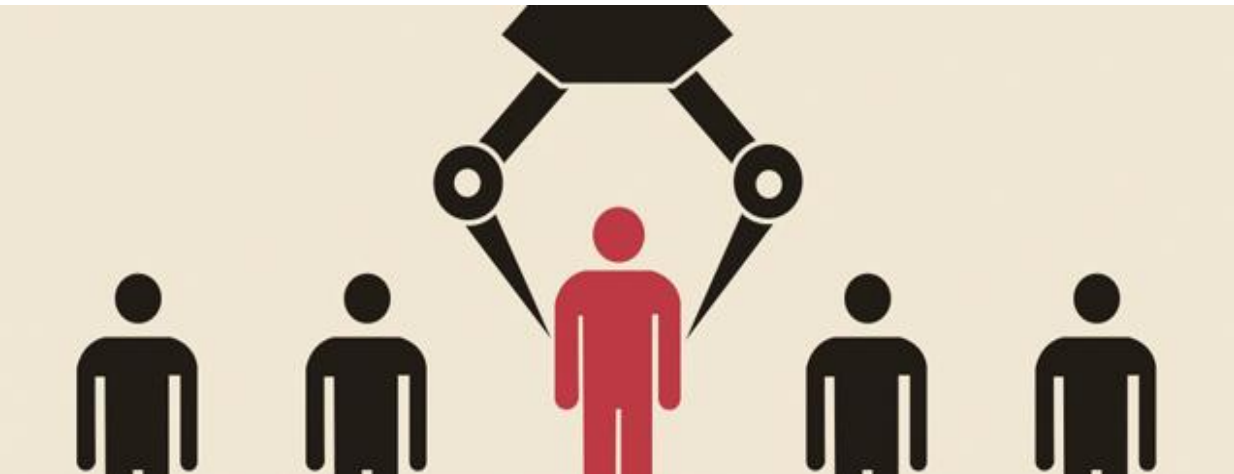
What and How?

The focus of an early look at data will differ somewhat depending on job function/role and depending on the timing of the review (you may look at different aspects of the data very early in the study compared to later in the study). An early look at data **CAN** include, but is not limited to :-

- ❖Look at CRF and external data via SDTM or raw datasets from an earlier stage (eg. SAS viewer)
- ❖Checking specific data points on CRF pages and/or queries, e.g. databases, query systems.
- ❖Checking dataset structures and variable attributes against specifications (eg. OpenCDISC/Pinnacle 21).
- ❖Look for and assess outlier values / unexpected values.
- ❖Data Visualisation – Utilise tools such as SAS JMP® Clinical
- ❖Identify data trends and assess them for appropriateness.
- ❖Ensure value range and number of missing values is logical.
- ❖Writing simple code to produce descriptive statistics for selected variables, e.g., freq or univariate.



AGE	AGE2	SEX	RACE
60	years	F	2
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67	years	M	1
67	years	F	2
68	years	M	1
68	years	M	1
68	years	F	2
68	years	M	1
68	years	F	2
68	years	F	2



Conclusion

In conclusion to achieve the ultimate goal of improving time to approval the following steps should be applied :-

- ❖Review and understand clinical data early to improve the clinical trial process.
- ❖Utilise the many tools available to produce simple and effective reports at the right time.
- ❖Strong communication skills and teamwork will enhance the decision making process.

Early Data Review Introduction

It is essential for data managers, statisticians, programmers and the wider clinical study team to have a solid understanding of the data that is used to analyze clinical trials. One means of acquiring knowledge about the data is to review it during early stages of a study – “**To Engage the Data**”. By reviewing data early members of a study team will be able to identify problems sooner and prevent or reduce propagation. Additionally teams will be better prepared for analyses and have greater confidence in the study results. The poster will address the ways in which performing early data review across all functions can enable clinical teams to make quicker, better and more informative decisions with the ultimate goal of improving time to approval.

Considerations

There are many things to consider when determining when to conduct a look at the data. There is no one trigger that is appropriate to every situation.

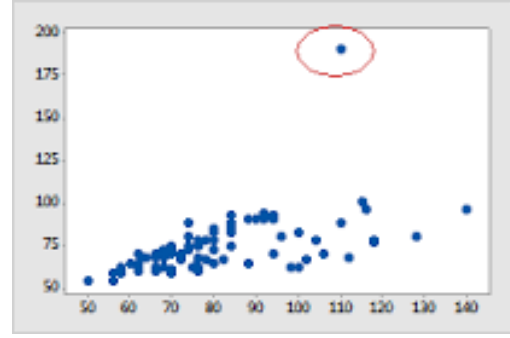
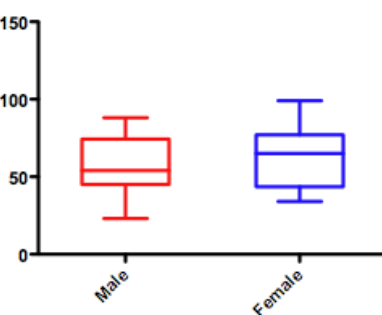
a) Your role in the processing of data.

b) Study Design

- ❖ Length of study
- ❖ Study phases
- ❖ Number of expected patients
- ❖ Number of visits
- ❖ Complexity of study

c) Other considerations.

- ❖ Rate of enrolment
- ❖ Cost
- ❖ The focus of the review – is the intention is to check dataset structure or to identify data trends or check value ranges.



When?

Early review of data is meant to occur at the earliest time point where the review will be meaningful and productive and to continue on an ongoing basis as often as necessary for you to have a strong understanding of the data. Exactly when this occurs might be different from study to study.

The earliest point at which a look at data can occur is the entry of data into the database but might be more likely be the first extraction of data into datasets and/or first receipt of external data.

Only 33% of drugs in phase II move to phase III

Benefits

- ❖Identify issues quicker
- ❖Prevent/Reduce Propagation
- ❖Mitigate Risks
- ❖Reduce Costs
- ❖Maintain accuracy of the data
- ❖Improved Decision Making
- ❖Trigger Go/NoGo Process
- ❖Better prepared for analyses
- ❖Greater Confidence in the study results



Clinical Study Team



Who?



Contact Details

Author : Graham Oakley
Email : graham.oakley@iconplc.com



Clinical Research