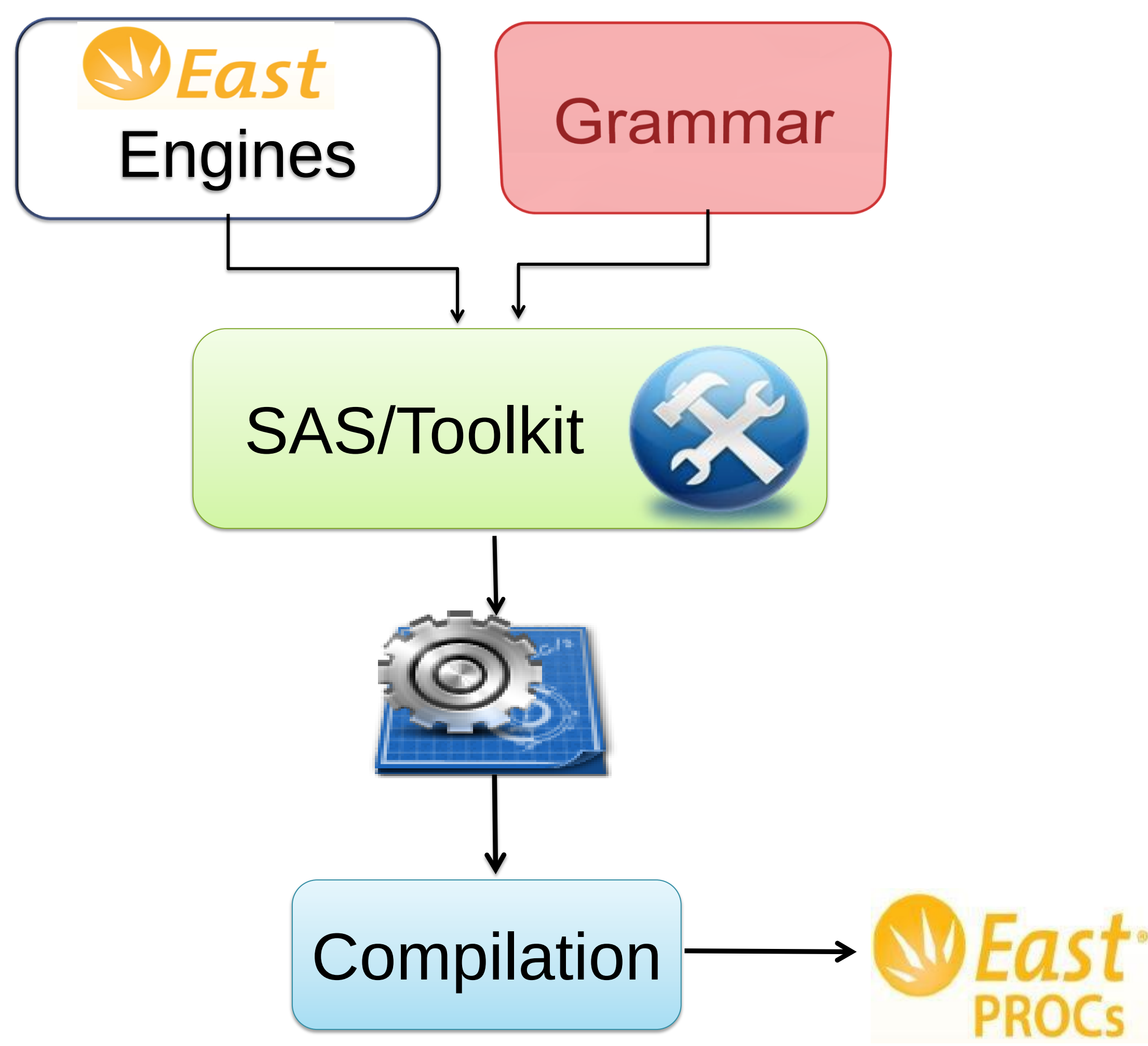


### Making of a PROC



### PROC EASTMONITOR FEATURES

- Design with **East®** and monitor with SAS ®!
- Industry-standard\* engines embedded
  - *every one of top-25 Pharma companies uses East. Do you?*
- PROC output aids advanced decision-making
- All kinds of endpoints: continuous, discrete, time-to-event and general
- Group sequential and Adaptive trials with sample size re-estimation

### OUTPUT

- Test statistic
- Recommend Continue / Stop for efficacy / futility
- RCI for treatment effect and repeated p-value (*Jennison and Turnbull (2000)*)
- Conditional power, Post-hoc power, Stopping boundaries etc.

### Example: Orlistat



Fat absorption an inhibitor. Trial to study effectiveness for weight loss and cardiovascular risk reduction.

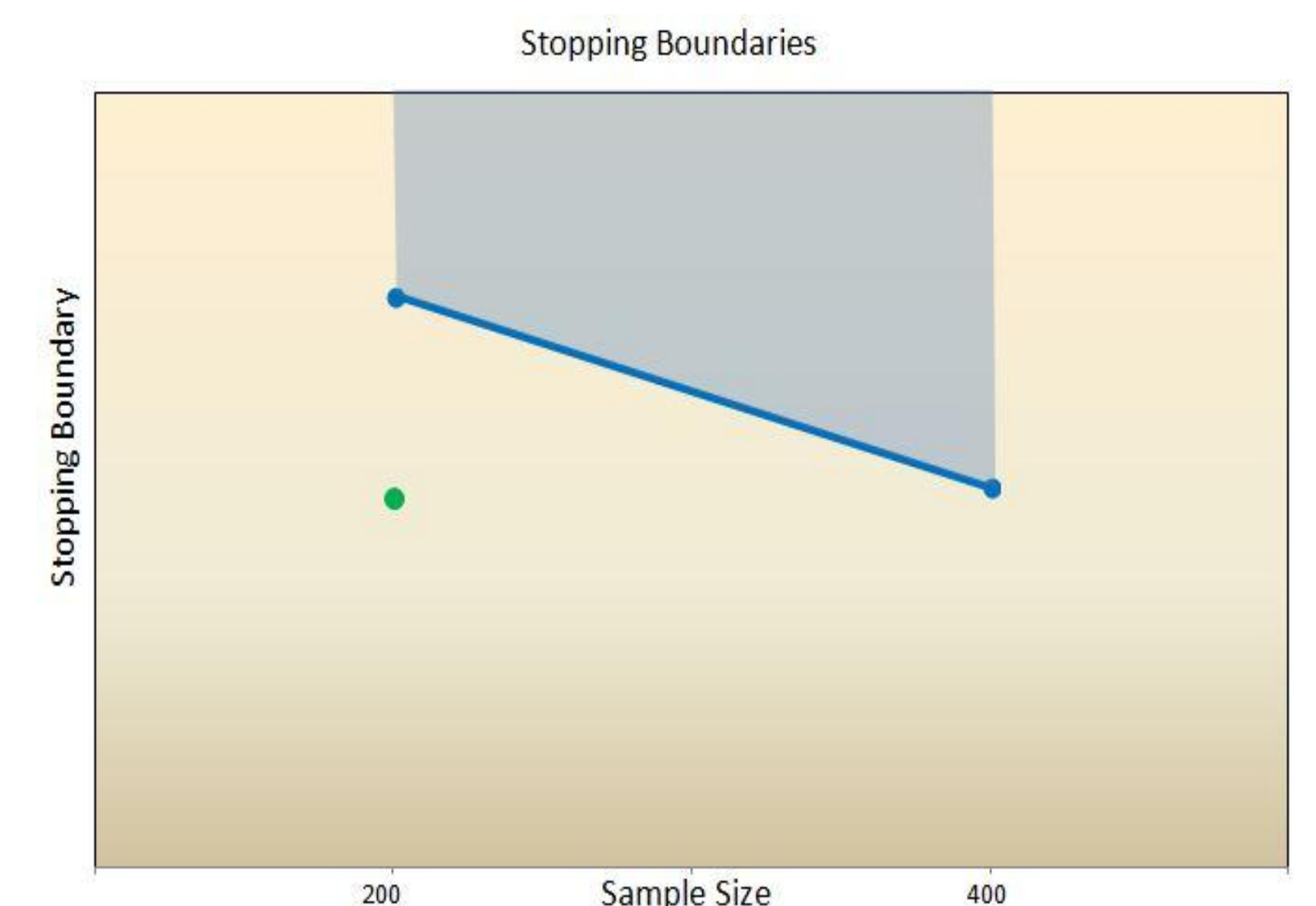
```
PROC EASTMONITOR DESIGN=Orlistat DATA=OrlistatLk1 ;
run;
```

INTERIM MONITORING: DIFFERENCE OF MEANS  
Design Input Parameters

Design ID : Des1  
Design DataSet : <INPUT.ORLISTAT>  
IM DataSet : <INPUT.ORLISTATLK1>

Test Parameters  
Design Type : Superiority  
No. of Looks : 2  
Test Type : 1-Sided  
Specified Alpha : 0.0250

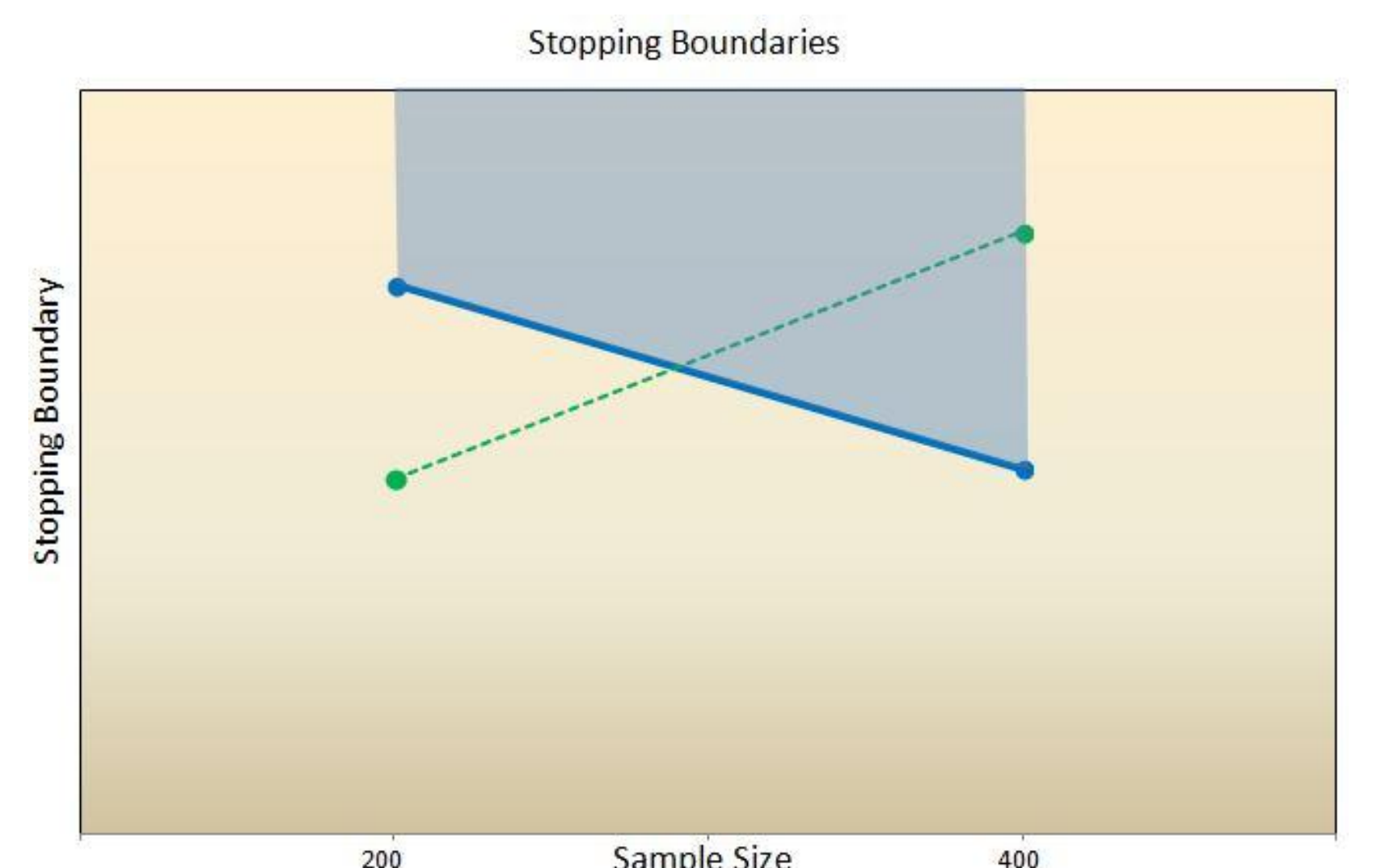
| Interim Monitoring Output |             |            |             | Test        |       |                | Efficacy |      |
|---------------------------|-------------|------------|-------------|-------------|-------|----------------|----------|------|
| Look                      | Fraction    | Cumulative | Sample Size | Statistic   |       |                |          |      |
| 1                         | 0.5         |            | 200         | 1.914       |       |                | 2.9625   |      |
| Look Cumulative           |             |            |             | Effect Size |       | Standard Error |          |      |
| No.                       | Sample Size |            |             |             |       | Lower          | Upper    |      |
| 1                         | 200         |            | 2,5000      |             | 1.306 | -1.37          | Infinity |      |
| Look Cumulative           |             |            |             | INLP        |       | CP             |          |      |
| No.                       | Sample Size |            |             |             |       |                |          |      |
| 1                         | 200         |            | 400         |             | 0.852 |                |          | 0.77 |



- Statistic 1.914 does not cross boundary.  
**Decision:** continue trial to second look.
- At second look Efficacy Boundary was crossed.  
**Decision: Efficacy!**

At the end of the trial, the PROC produced the following additional output:

**Final Inference**  
Final Outputs at Look : 2  
Adj. p-value : 0.001807  
Adj. Pt. Est. for Effect Size : 3.007  
Adj. 95.00% CI for Effect Size  
Upper confidence bound : 4.8577  
Lower confidence bound : 1.0603  
Post-Hoc Power : 0.9



### Clinical Trial Workflow

