

## RECOVERY DATA

Animal	Baseline	Post-Dose		Recovery
		1 hour post-dose	4 hours post-dose	
1001	88	94	92	94
1002	90	96	94	96
1003	104	110	108	
1004	98	104	106	
<b>Mean</b>	<b>95</b>	<b>101</b>	<b>100</b>	<b>95</b>

Interpretation 1: Heart rate was increased 5-6 bpm during the first 4 hours post-dose and returned to baseline values during recovery.

Interpretation 2: Heart rate was increased 5-6 bpm during the first 4 hours post-dose. Of those animals that continued through recovery, heart rate remained 6 bpm higher than baseline.

Animal	Baseline	Post-Dose		Recovery
		1 hour post-dose	4 hours post-dose	
1001	89	95	94	89
1002	91	97	96	91
1003	75	81	80	
1004	81	87	86	
<b>Mean</b>	<b>84</b>	<b>90</b>	<b>89</b>	<b>90</b>

Interpretation 1: Heart rate was increased 5-6 bpm during the first 4 hours post-dose and remained 6 bpm higher than baseline during recovery.

Interpretation 2: Heart rate was increased 5-6 bpm during the first 4 hours post-dose. Of those animals that continued through recovery, heart rate returned to values observed at baseline.

Simply interpreting results based on recovery means from a subset of animals can be misleading. Another issue arises if one applies a statistical analysis to recovery data. Typically, main study sample sizes provide sufficient power that conclusions about primary endpoints can be made with confidence. Recovery data is often only collected on a small subset of main study animals and, as such, an analysis of recovery data is often under-powered for meaningful interpretation.

	Post-Dose		Recovery
	1 hour post-dose	4 hours post-dose	
N	6/group	6/group	3/group
<b>Control Mean</b>	<b>85</b>	<b>83</b>	<b>83</b>
<b>TA Mean</b>	<b>90*</b>	<b>89*</b>	<b>88</b>

In the example above, if recovery data were statistically analyzed, the results could easily be misinterpreted as a significant increase during the post-dose period that “goes away” during recovery. More likely, there is simply insufficient power with the recovery sample size to detect statistical significance.

