

E. SUMMARY OF CLINICAL RESULTS

A preliminary accountability table for 230 eyes that have undergone a single treatment is provided in Table 1.1.E-1 below.

Table 1.1.E-1: Accountability

	1 Month	3 Months	6 Months	9 Months*	12 Months
Completed Visit	168	156	80	18	7
Missed Visit but Completed Later Visit	30	6	6	3	0
Discontinued	0	0	0	0	0
Not Eligible for Interval	19	50	127	209	223
Missed Visit and No Data at Any Later Visit	13	18	17	0	0
TOTAL EYES	230	230	230	230	230
Total Eligible For Visit	211	180	103	21	7
% Accountability	93.8%	89.9%	83.3%	100.0%	100.0%

* The 9-month postop visit is an optional visit.

Accountability was calculated using the following formula:

$$\% \text{ Accountability} = \frac{\text{Completed Visit} + \text{Missed Visit but Completed Later Visit}}{(\text{Enrolled} - \text{Discontinued} - \text{Not Yet Eligible})}$$

The accountability is based on data entered into the database as of October 1, 1998. Outstanding visit data are still being obtained from co-management doctors and the investigative site and entered into the database in preparation for analyzing and submitting the data from this study for the PMA. The declining accountability at 3 and 6 months is due to outstanding data and patients who are eligible for these postoperative visits but are still within the visit window for completing the visit.

Refractive stability was analyzed for eyes that have manifest refractions at 1, 3, 6, and/or 9 months as well as for those eyes that have sequential MRSE data at 1, 3,