



January 6, 2009

PMA Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

RE: P050034 – Amendment 19
VisionCare Ophthalmic Technologies Implantable Miniature Telescope
IMT (by Dr. Isaac Lipshitz)TM

Dear Sir or Madam,

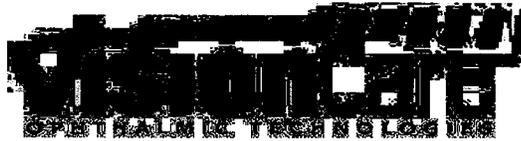
Please find enclosed six (6) copies of Amendment 19 to P050034, for the Implantable Miniature Telescope (IMT).

This amendment provides responses to a list of additional analyses requested by the Division of Ophthalmic and ENT Devices (DOENTD) via email communication on December 19, 2008. In addition to responding to these specific requests, VisionCare has also provided three summary analyses. The tables are presented immediately following the responses to DOENTD's request.

Thank you for your consideration of this PMA P050034 as amended. If you have any questions or need any additional information during your review, please contact me at (949) 715-0609 (phone), or by fax at (949) 715-0610, or by email at judy@clinregconsulting.com.

Sincerely,

Judy F. Gordon, D.V.M.
Regulatory Consultant to VisionCare Ophthalmic Technologies, Inc.



P050034

AMENDMENT 019
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE™
(IMT BY DR. ISAAC LIPSHITZ)

VOLUME I OF I

JANUARY 6, 2009

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P050034 AMENDMENT 019
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE

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P050034 AMENDMENT 19
VISIONCARE OPHTHALMIC TECHNOLOGIES, INC.
IMPLANTABLE MINIATURE TELESCOPE (IMT)
RESPONSE TO ANALYSES REQUESTED BY FDA ON 19 DECEMBER 2008

The following information is provided in response to a list of additional analyses requested by FDA via email communication on December 19, 2008. In addition to responding to FDA's specific requests, VisionCare has also provided three summary analyses. The tables are presented immediately following the responses to FDA's request.

- 1. Please provide an analysis of mean postoperative BCVA for all time intervals reported in the primary protocol and long-term protocol beginning with the one-year mark stratified by preoperative BCVA for the restricted cohort (non-guttata eyes, 65 or older, ACD ≥ 3.0 mm, cornea-trained specialist).*

An analysis of mean postoperative BCDVA for all time intervals reported in Protocol IMT-002 is presented in Table 1.1 for three cohorts:

- IMT-implanted eyes
- Cohort A, consisting of eyes of subjects age ≥ 65 , with no guttata, with ACD ≥ 3.0 mm, and implanted by cornea specialist (restricted cohort); and
- Cohort B, consisting of the IMT-implanted eyes excluded from Cohort A.

The visual acuity outcomes are stratified and presented for preoperative BCDVA categories of 20/80 to 20/160+, 20/160 to 20/400, and $< 20/400$.

This analysis is repeated for the subjects enrolled in Protocol IMT-002-LTM, from baseline through 12, 18, 24, 36, 42 and 48 months in Table 1.2.

As shown in Table 1.1, BCDVA improved for each of the cohorts of eyes presented, and for each of the baseline BCDVA groups (BCDVA 20/160+, 20/160 to 20/400, and $< 20/400$). As previously shown in P050034, eyes with poorer preoperative BCDVA experienced greater improvements in BCDVA postoperatively.

Improvements in BCDVA in the IMT-002-LTM study, which was originally designed to serve as a post-approval surveillance study but was implemented before PMA approval, were generally maintained over 48 months. Modest decreases in BCDVA were observed at 42 and 48 months, as compared to the 24 and 36 month visits. Although not presented in this table, visual acuity also decreased modestly in fellow eyes over the same time period, as would be expected in patients with age related macular degeneration.

TABLE 1.1
MEAN BCDVA STRATIFIED BY PREOPERATIVE BCDVA
IMT-IMPLANTED EYES, IMT-002 STUDY

OVERALL	206 20/312 (20/334, 20/291)	204 20/187 (20/203, 20/173)	200 20/149 (20/160, 20/140)	201 20/146 (20/157, 20/136)	195 20/145 (20/156, 20/134)	193 20/141 (20/152, 20/131)	179 20/144 (20/156, 20/133)	173 20/149 (20/161, 20/138)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	15 20/123 (20/136, 20/111)	15 20/127 (20/189, 20/85)	15 20/102 (20/145, 20/72)	15 20/94 (20/138, 20/64)	15 20/112 (20/165, 20/76)	15 20/103 (20/154, 20/69)	14 20/101 (20/148, 20/69)	14 20/98 (20/134, 20/71)
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	125 20/259 (20/271, 20/247)	123 20/167 (20/183, 20/152)	121 20/134 (20/144, 20/124)	122 20/130 (20/140, 20/121)	119 20/129 (20/140, 20/118)	115 20/127 (20/138, 20/116)	107 20/126 (20/137, 20/115)	104 20/132 (20/145, 20/121)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	66 20/548 (20/574, 20/524)	66 20/254 (20/288, 20/223)	64 20/201 (20/223, 20/181)	64 20/202 (20/226, 20/180)	61 20/195 (20/221, 20/172)	63 20/183 (20/206, 20/163)	58 20/201 (20/229, 20/176)	55 20/207 (20/232, 20/184)

TABLE 1.1 (CONTINUED)
MEAN BCDVA STRATIFIED BY PREOPERATIVE BCDVA
IMT-IMPLANTED EYES, IMT-002 STUDY

OVERALL	33 20/349 (20/418, 20/290)	33 20/201 (20/238, 20/170)	32 20/181 (20/220, 20/149)	33 20/175 (20/211, 20/145)	30 20/169 (20/205, 20/139)	31 20/147 (20/179, 20/122)	29 20/148 (20/183, 20/119)	27 20/164 (20/203, 20/132)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	3 20/110 (20/163, 20/74)	3 20/102 (20/233, 20/44)	3 20/87 (20/118, 20/65)	3 20/94 (20/136, 20/65)	3 20/126 (20/281, 20/57)	3 20/74 (20/138, 20/39)	3 20/78 (20/158, 20/39)	3 20/85 (20/149, 20/48)
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	16 20/292 (20/330, 20/259)	16 20/229 (20/291, 20/180)	15 20/198 (20/271, 20/145)	16 20/171 (20/230, 20/128)	15 20/166 (20/230, 20/120)	14 20/148 (20/197, 20/111)	13 20/132 (20/183, 20/96)	12 20/153 (20/202, 20/116)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	14 20/545 (20/603, 20/494)	14 20/201 (20/258, 20/156)	14 20/192 (20/250, 20/147)	14 20/204 (20/269, 20/155)	12 20/185 (20/248, 20/138)	14 20/171 (20/228, 20/128)	13 20/191 (20/261, 20/140)	12 20/206 (20/294, 20/145)
OVERALL	173 20/305 (20/328, 20/284)	171 20/185 (20/202, 20/169)	168 20/144 (20/155, 20/134)	168 20/141 (20/152, 20/131)	165 20/141 (20/153, 20/130)	162 20/139 (20/151, 20/128)	150 20/143 (20/156, 20/131)	146 20/146 (20/159, 20/134)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	12 20/126 (20/143, 20/112)	12 20/134 (20/222, 20/80)	12 20/106 (20/166, 20/68)	12 20/94 (20/153, 20/57)	12 20/108 (20/177, 20/66)	12 20/112 (20/185, 20/68)	11 20/109 (20/176, 20/67)	11 20/102 (20/153, 20/67)
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	109 20/254 (20/267, 20/242)	107 20/160 (20/176, 20/145)	106 20/127 (20/136, 20/118)	106 20/125 (20/134, 20/117)	104 20/124 (20/135, 20/114)	101 20/124 (20/136, 20/113)	94 20/125 (20/137, 20/114)	92 20/130 (20/143, 20/118)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	52 20/549 (20/579, 20/521)	52 20/270 (20/313, 20/233)	50 20/204 (20/229, 20/181)	50 20/201 (20/229, 20/177)	49 20/197 (20/228, 20/171)	49 20/187 (20/214, 20/164)	45 20/204 (20/236, 20/175)	43 20/207 (20/234, 20/183)

TABLE 1.2
MEAN BCDVA STRATIFIED BY PREOPERATIVE BCDVA
IMT-IMPLANTED EYES, IMT-002-LTM STUDY

OVERALL	123 20/306 (20/335, 20/280)	122 20/139 (20/152, 20/126)	117 20/145 (20/160, 20/132)	116 20/145 (20/159, 20/133)	74 20/156 (20/175, 20/139)	104 20/174 (20/197, 20/154)	96 20/171 (20/191, 20/152)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	11 20/125 (20/143, 20/109)	11 20/116 (20/202, 20/67)	10 20/111 (20/191, 20/65)	10 20/104 (20/163, 20/66)	8 20/96 (20/128, 20/72)	10 20/121 (20/190, 20/77)	10 20/126 (20/199, 20/79)
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	74 20/260 (20/277, 20/244)	73 20/123 (20/135, 20/112)	71 20/124 (20/137, 20/113)	69 20/126 (20/140, 20/114)	47 20/146 (20/167, 20/127)	65 20/162 (20/190, 20/138)	58 20/152 (20/174, 20/134)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	38 20/546 (20/577, 20/515)	38 20/183 (20/214, 20/156)	36 20/213 (20/250, 20/181)	37 20/207 (20/234, 20/182)	19 20/225 (20/279, 20/181)	29 20/233 (20/281, 20/192)	28 20/240 (20/292, 20/197)

TABLE 1.2 (CONTINUED)
MEAN BCDVA STRATIFIED BY PREOPERATIVE BCDVA
IMT-IMPLANTED EYES, IMT-002-LTM STUDY

OVERALL	17 20/403 (20/486, 20/335)	16 20/137 (20/175, 20/108)	16 20/153 (20/199, 20/118)	16 20/162 (20/209, 20/126)	10 20/174 (20/289, 20/105)	14 20/180 (20/282, 20/115)	13 20/161 (20/266, 20/98)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	0	0	0	0	0	0	0
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	9 20/303 (20/357, 20/256)	8 20/137 (20/189, 20/99)	8 20/134 (20/191, 20/93)	8 20/143 (20/209, 20/98)	6 20/180 (20/463, 20/70)	8 20/203 (20/438, 20/95)	7 20/166 (20/422, 20/66)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	8 20/557 (20/629, 20/494)	8 20/138 (20/216, 20/88)	8 20/175 (20/275, 20/112)	8 20/183 (20/280, 20/120)	4 20/166 (20/294, 20/94)	6 20/153 (20/284, 20/82)	6 20/155 (20/310, 20/78)
OVERALL	106 20/293 (20/323, 20/266)	106 20/139 (20/153, 20/126)	101 20/144 (20/160, 20/129)	100 20/143 (20/158, 20/129)	64 20/153 (20/172, 20/136)	90 20/173 (20/197, 20/152)	83 20/172 (20/193, 20/154)
EYES WITH BCDVA OF 20/80 TO 20/160+ PREOPERATIVELY	11 20/125 (20/143, 20/109)	11 20/116 (20/202, 20/67)	10 20/111 (20/191, 20/65)	10 20/104 (20/163, 20/66)	8 20/96 (20/128, 20/72)	10 20/121 (20/190, 20/77)	10 20/126 (20/199, 20/79)
EYES WITH BCDVA OF 20/160 TO 20/400 PREOPERATIVELY	65 20/255 (20/273, 20/238)	65 20/122 (20/135, 20/110)	63 20/123 (20/136, 20/111)	61 20/124 (20/139, 20/111)	41 20/142 (20/159, 20/126)	57 20/157 (20/184, 20/134)	51 20/151 (20/169, 20/134)
EYES WITH BCDVA OF <20/400 PREOPERATIVELY	30 20/542 (20/581, 20/507)	30 20/197 (20/232, 20/167)	28 20/225 (20/268, 20/189)	29 20/213 (20/242, 20/188)	15 20/243 (20/311, 20/191)	23 20/259 (20/312, 20/216)	22 20/270 (20/322, 20/227)

1.a. Please provide a data line listing for each subject in this restricted cohort that includes all of the parameters defined in number one above, along with their resultant ECD count and % change from baseline.

A data line listing for the restricted cohort (Cohort A in Tables 1.1 and 1.2), consisting of subjects age ≥ 65 , with no guttata, ACD ≥ 3.0 mm, and implanted by cornea specialists is provided in Table 1.a. This listing also identifies whether the subject achieved the primary effectiveness endpoint (≥ 2 -line improvement in either BCDVA or BCNVA) as well as whether the subject achieved a 2-line improvement in BCDVA.

**TABLE 1.A
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES**

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Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y		Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.24 (20/348)	1.04 (20/219)	0.98 (20/191)	0.92 (20/166)	0.78 (20/121)	0.88 (20/152)	0.90 (20/160)		1.04 (20/219)	0.88 (20/152)
ECD	2642		2274	2326	1855	1929	1011		508	660
ECD % Change			-13.9%	-11.9%	-29.8%	-27.0%	-61.7%		-80.8%	-75.0%
Met Efficacy Endpoint		Y	Y		Y	Y	Y			
≥2-Line Gain in BCDVA		Y	N		Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.34 (20/438)	1.04 (20/219)	1.22 (20/332)		1.00 (20/200)	1.06 (20/230)	0.98 (20/191)			
ECD	2385		1950		1599	1821	2237			
ECD % Change			-18.3%		-32.9%	-23.6%	-6.2%			
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y	Y	
BCDVA, LogMAR (Snellen Equ.)	1.50 (20/630)	0.66 (20/91)	0.82 (20/132)	0.74 (20/110)	0.68 (20/96)	0.82 (20/132)	0.86 (20/145)	0.92 (20/166)	0.96 (20/182)	
ECD	2322	1932	1650	1856	1948	1837	1821	1357	1637	
ECD % Change		-16.8%	-28.9%	-20.0%	-16.1%	-20.9%	-21.5%	-41.6%	-29.5%	
Met Efficacy Endpoint		N	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	Y	N	Y	Y	N	N	N	N
BCDVA, LogMAR (Snellen Equ.)	1.20 (20/320)	1.24 (20/348)	1.00 (20/200)	1.06 (20/230)	1.00 (20/200)	1.00 (20/200)	1.16 (20/289)	1.70 (20/1000)	1.62 (20/834)	1.70 (20/1000)
ECD	2908	432	452	397	361	351				
ECD % Change		-85.1%	-84.4%	-86.4%	-87.6%	-87.9%				
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.48 (20/604)	0.86 (20/145)	0.84 (20/138)	0.86 (20/145)	0.86 (20/145)	1.10 (20/250)	1.02 (20/209)			
ECD	2607	2284	2469	2203	2486	2477	2544			
ECD % Change		-12.4%	-5.3%	-15.5%	-4.6%	-5.0%	-2.4%			

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y		Y
BCDVA, LogMAR (Snellen Equ.)	1.36 (20/458)	0.66 (20/91)	0.64 (20/87)	0.60 (20/80)	0.60 (20/80)	0.62 (20/83)	0.74 (20/110)	0.94 (20/174)		0.98 (20/191)
ECD	2038	1576	1452	1405	1400	1439	1351	1180		1276
ECD % Change		-22.7%	-28.7%	-31.1%	-31.3%	-29.4%	-33.7%	-42.1%		-37.4%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.00 (20/200)	0.62 (20/83)	0.62 (20/83)	0.70 (20/100)	0.68 (20/96)	0.62 (20/83)	0.62 (20/83)	0.76 (20/115)	0.72 (20/105)	0.78 (20/121)
ECD	2260	2277	2233	2174	2061	2180	2896	2070	2085	1975
ECD % Change		0.8%	-1.2%	-3.8%	-8.8%	-3.6%	28.1%	-8.4%	-7.7%	-12.6%
Met Efficacy Endpoint		N	N	N	N	N	N			
≥2-Line Gain in BCDVA		N	N	N	N	N	N			
BCDVA, LogMAR (Snellen Equ.)	0.70 (20/100)	0.68 (20/96)	0.70 (20/100)	0.96 (20/182)	0.64 (20/87)	0.70 (20/100)	0.74 (20/110)			
ECD	2836	2535	2530	2558	2598	2691	2492			
ECD % Change		-10.6%	-10.8%	-9.8%	-8.4%	-5.1%	-12.1%			
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	N	N	Y	Y	N			
BCDVA, LogMAR (Snellen Equ.)	0.70 (20/100)	0.58 (20/76)	0.72 (20/105)	0.74 (20/110)	0.44 (20/55)	0.46 (20/58)	0.58 (20/76)			
ECD	2651	2628	2001	1970	2066	1962	2102			
ECD % Change		-0.9%	-24.5%	-25.7%	-22.1%	-26.0%	-20.7%			
Met Efficacy Endpoint		N	N	N						
≥2-Line Gain in BCDVA		N	N	N						
BCDVA, LogMAR (Snellen Equ.)	1.12 (20/264)	1.46 (20/577)	1.54 (20/693)	1.60 (20/800)						
ECD	2650	3126	2857	3008						
ECD % Change		18.0%	7.8%	13.5%						

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y		Y					
≥2-Line Gain in BCDVA		Y	Y		Y					
BCDVA, LogMAR (Snellen Equ.)	1.34 (20/438)	1.00 (20/200)	1.00 (20/200)		0.98 (20/191)					
ECD	2493	2495	2350		2241		2201			
ECD % Change		0.1%	-5.7%		-10.1%		-11.7%			
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	N	N	
BCDVA, LogMAR (Snellen Equ.)	1.24 (20/348)	0.76 (20/115)	0.84 (20/138)	0.96 (20/182)	0.92 (20/166)	0.92 (20/166)	0.94 (20/174)	1.40 (20/500)	1.18 (20/303)	
ECD	2592	2646	2585	2324	1701	2015	1697	1934	2415	
ECD % Change		2.1%	-0.3%	-10.4%	-34.4%	-22.3%	-34.5%	-25.4%	-6.8%	
Met Efficacy Endpoint		Y	N	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	N	Y	Y	N	N			
BCDVA, LogMAR (Snellen Equ.)	1.34 (20/438)	1.24 (20/348)	1.28 (20/381)	1.14 (20/276)	1.12 (20/264)	1.18 (20/303)	1.40 (20/500)			
ECD	2065	1307	1554	971		804	1294			
ECD % Change		-36.7%	-24.8%	-53.0%		-61.1%	-37.4%			
Met Efficacy Endpoint		Y	N	Y	Y					
≥2-Line Gain in BCDVA		N	N	N	N					
BCDVA, LogMAR (Snellen Equ.)	1.28 (20/381)	1.22 (20/332)	1.24 (20/348)	1.26 (20/364)	1.24 (20/348)					
ECD	2081	1623	2076	1688	1858					
ECD % Change		-22.0%	-0.2%	-18.9%	-10.7%					
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	N	Y	Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.54 (20/693)	1.28 (20/381)	1.36 (20/458)	1.18 (20/303)	1.24 (20/348)	1.28 (20/381)	1.30 (20/400)			
ECD	2833	2513	2821		2821	2616	2833			
ECD % Change		-11.3%	-0.4%		-0.4%	-7.7%	-0.0%			

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.02 (20/209)	0.62 (20/83)	0.56 (20/73)	0.64 (20/87)	0.58 (20/76)	0.64 (20/87)			
ECD	2277	2001	1962	1941	1936	1930			
ECD % Change		-12.1%	-13.8%	-14.7%	-15.0%	-15.2%			
Met Efficacy Endpoint		N	Y	N	Y	Y	Y		
≥2-Line Gain in BCDVA		N	Y	N	Y	Y	Y		
BCDVA, LogMAR (Snellen Equ.)	0.82 (20/132)	0.66 (20/91)	0.60 (20/80)	0.70 (20/100)	0.62 (20/83)	0.62 (20/83)	0.56 (20/73)		
ECD	2153	2324	2290	2400	2345	2175	2262		
ECD % Change		7.9%	6.3%	11.4%	8.9%	1.0%	5.0%		
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y		
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.14 (20/276)	0.84 (20/138)	0.78 (20/121)	0.70 (20/100)	0.58 (20/76)	0.54 (20/69)	0.64 (20/87)	0.34 (20/44)	0.32 (20/42)
ECD	2843	1625	1622	1647	1690	1726	1616	1800	1865
ECD % Change		-42.8%	-42.9%	-42.0%	-40.6%	-39.3%	-43.2%	-36.7%	-34.4%
Met Efficacy Endpoint		N	Y	Y	Y	Y	Y		
≥2-Line Gain in BCDVA		N	Y	Y	Y	Y	Y		
BCDVA, LogMAR (Snellen Equ.)	1.04 (20/219)	1.14 (20/276)	0.70 (20/100)	0.68 (20/96)	0.62 (20/83)	0.42 (20/53)	0.66 (20/91)		
ECD	2134	1795	1495	2122	1402	1451	1365		
ECD % Change		-15.9%	-29.9%	-0.6%	-34.3%	-32.0%	-36.0%		
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y		
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.52 (20/662)	1.18 (20/303)	1.14 (20/276)	1.16 (20/289)	1.24 (20/348)	1.22 (20/332)	1.28 (20/381)	1.22 (20/332)	1.22 (20/332)
ECD	1994	1971	1805	1901	2083	1827	1607	1665	1686
ECD % Change		-1.1%	-9.5%	-4.7%	4.5%	-8.4%	-19.4%	-16.5%	-15.5%

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.48 (20/604)	0.92 (20/166)	0.96 (20/182)	0.90 (20/160)	1.06 (20/230)	0.70 (20/100)	0.78 (20/121)			
ECD	2267	2313	2154	1923	2343	2153	2034			
ECD % Change		2.0%	-5.0%	-15.2%	3.3%	-5.1%	-10.3%			
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y		Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.36 (20/458)	0.80 (20/125)	0.86 (20/145)	0.96 (20/182)	0.78 (20/121)	0.80 (20/125)	0.88 (20/152)		0.70 (20/100)	0.68 (20/96)
ECD	2651	1959	1961	2011	2051	1851	2109		1287	1673
ECD % Change		-26.1%	-26.0%	-24.2%	-22.6%	-30.2%	-20.5%		-51.5%	-36.9%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.40 (20/500)	0.88 (20/152)	0.82 (20/132)	0.88 (20/152)	0.60 (20/80)	0.74 (20/110)	0.76 (20/115)	0.72 (20/105)	0.58 (20/76)	0.50 (20/63)
ECD	2694	2427	2283	2453	2520	2249	2447	2173	2270	2232
ECD % Change		-9.9%	-15.2%	-8.9%	-6.4%	-16.5%	-9.2%	-19.3%	-15.7%	-17.1%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.30 (20/400)	1.12 (20/264)	1.00 (20/200)	0.86 (20/145)	0.96 (20/182)	0.92 (20/166)	0.86 (20/145)	0.78 (20/121)	0.86 (20/145)	0.62 (20/83)
ECD	2428	2395	2452	2255	2159	2299	2366	2079	2087	2058
ECD % Change		-1.4%	1.0%	-7.1%	-11.1%	-5.3%	-2.6%	-14.4%	-14.1%	-15.3%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y		Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.48 (20/604)	1.04 (20/219)	0.98 (20/191)	0.88 (20/152)	0.82 (20/132)	0.98 (20/191)	0.86 (20/145)		0.72 (20/105)	0.78 (20/121)
ECD	2326	1953	1862	2231	2226	2275	1814		2242	1866
ECD % Change		-16.0%	-19.9%	-4.0%	-4.3%	-2.2%	-22.0%		-3.6%	-19.7%

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	N	Y	Y	N	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.46 (20/577)	1.20 (20/320)	1.22 (20/332)	1.30 (20/400)	1.12 (20/264)	1.26 (20/364)	1.30 (20/400)	1.10 (20/250)	1.12 (20/264)	1.18 (20/303)
ECD	2641	1186	1598	1739	1524	1704	1589	1628	1731	1721
ECD % Change		-55.1%	-39.5%	-34.2%	-42.3%	-35.5%	-39.8%	-38.4%	-34.5%	-34.8%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	Y	Y	Y	Y	Y	Y	Y	Y
BCDVA, LogMAR (Snellen Equ.)	1.26 (20/364)	1.18 (20/303)	1.00 (20/200)	0.98 (20/191)	1.04 (20/219)	1.04 (20/219)	1.04 (20/219)	0.90 (20/160)	0.92 (20/166)	0.96 (20/182)
ECD	2414	2653	2326	2460	2221	2310	2015	2282	1610	2376
ECD % Change		9.9%	-3.7%	1.9%	-8.0%	-4.3%	-16.5%	-5.5%	-33.3%	-1.6%
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y	Y		
BCDVA, LogMAR (Snellen Equ.)	1.10 (20/250)	0.72 (20/105)	0.78 (20/121)	0.66 (20/91)	0.72 (20/105)	0.68 (20/96)	0.68 (20/96)	0.58 (20/76)		
ECD	2758	2488	2404	2672	2586	2643	2708	2330		
ECD % Change		-9.8%	-12.8%	-3.1%	-6.2%	-4.2%	-1.8%	-15.5%		
Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		N	N	N	N	N	N			
BCDVA, LogMAR (Snellen Equ.)	1.08 (20/240)	1.08 (20/240)	1.04 (20/219)	0.90 (20/160)	0.90 (20/160)	1.00 (20/200)	1.06 (20/230)			
ECD	2813	2602	2634	2314	2547	2609	2138			
ECD % Change		-7.5%	-6.4%	-17.8%	-9.5%	-7.3%	-24.0%			
Met Efficacy Endpoint		Y	N	Y	N	N	N			
≥2-Line Gain in BCDVA		Y	N	Y	N	N	N			
BCDVA, LogMAR (Snellen Equ.)	1.20 (20/320)	0.96 (20/182)	1.06 (20/230)	0.94 (20/174)	1.22 (20/332)	1.24 (20/348)	1.08 (20/240)			
ECD	2728	2170	2445	1647	2005	2110	1630			
ECD % Change		-20.5%	-10.4%	-39.6%	-26.5%	-22.7%	-40.3%			

TABLE 1.A (CONTINUED)
DATA LINE LISTING
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002 AND IMT-002-LTM STUDIES

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Met Efficacy Endpoint		Y	Y	Y	Y	Y	Y			
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y	Y			
BCDVA, LogMAR (Snellen Equ.)	1.28 (20/381)	0.94 (20/174)	0.92 (20/166)	0.94 (20/174)	0.92 (20/166)	0.76 (20/115)	0.96 (20/182)			
ECD	2263	1634	1322	1429	1507		1599			
ECD % Change		-27.8%	-41.6%	-36.8%	-33.4%		-29.3%			
Met Efficacy Endpoint		Y	Y	Y	Y	Y				
≥2-Line Gain in BCDVA		Y	Y	Y	Y	Y				
BCDVA, LogMAR (Snellen Equ.)	1.50 (20/630)	0.98 (20/191)	0.98 (20/191)	1.00 (20/200)	0.94 (20/174)	0.98 (20/191)				
ECD	2857		2370	2425	2412	2104				
ECD % Change			-17.0%	-15.1%	-15.6%	-26.3%				
Met Efficacy Endpoint			Y							
≥2-Line Gain in BCDVA			Y					N	N	
BCDVA, LogMAR (Snellen Equ.)	1.14 (20/276)		0.86 (20/145)					1.00 (20/200)	1.16 (20/289)	
ECD	1983		1843					1740		
ECD % Change			-7.1%					-12.2%		

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

a. *The same Table 2 (from most recent email—ECD and % loss over time), but extended out to the end of the longer follow-up group. Please include the following additional information in the table.*

- i) *95% upper and lower confidence limits on all mean ECDs and percent changes in the table.*
- ii) *Number and percent of eyes below 1000 and below 750 at each visit.*

Tables 2.A.1 and 2.A.2 present mean ECD and mean % change in ECD from baseline with 95% confidence intervals and standard deviations, as well as the number and percent of subjects with ECD below 1000 and 750 cells/mm² for each visit. Table 2.A.1 shows these statistics for Protocol IMT-002 while Table 2.A.2 presents the same information for subjects enrolled in Protocol IMT-002-LTM. Data are presented for the following three cohorts of eyes:

- IMT-implanted eyes
- Cohort A, consisting of eyes of subjects age \geq 65, with no guttata, with ACD \geq 3.0 mm, and implanted by cornea specialist (restricted cohort); and
- Cohort B, consisting of the IMT-implanted eyes excluded from Cohort A.

These are the same cohorts of eyes as presented in our response to Item 1.

TABLE 2.A.1
ENDOTHELIAL CELL DENSITY
IMT-IMPLANTED EYES
IMT-002 STUDY

N	206	193	198	190	186	180	171
ECD (MEAN, SD)	2496 (354)	1995 (585)	1937 (580)	1891 (572)	1871 (592)	1878 (618)	1808 (596)
95%CI	(2447, 2545)	(1912, 2078)	(1856, 2018)	(1809, 1973)	(1786, 1957)	(1787, 1969)	(1718, 1898)
ECD % CHANGE (MEAN, SD)		-20% (21%)	-22% (21%)	-24% (21%)	-25% (21%)	-25% (22%)	-28% (22%)
95%CI		(-23%, -17%)	(-25%, -19%)	(-27%, -21%)	(-28%, -22%)	(-28%, -22%)	(-31%, -24%)
ECD < 750 CELLS/MM²	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)
ECD < 1000 CELLS/MM²	0 (0%)	16 (8%)	17 (9%)	16 (8%)	21 (11%)	21 (12%)	19 (11%)
N	33	29	33	29	30	28	27
ECD (MEAN, SD)	2472 (288)	2099 (554)	2063 (497)	2015 (528)	2018 (493)	1983 (522)	1992 (492)
95%CI	(2370, 2574)	(1888, 2310)	(1887, 2239)	(1815, 2216)	(1834, 2202)	(1781, 2186)	(1797, 2187)
ECD % CHANGE (MEAN, SD)		-15% (21%)	-16% (18%)	-18% (20%)	-19% (19%)	-20% (20%)	-19% (19%)
95%CI		(-23%, -7%)	(-23%, -10%)	(-26%, -10%)	(-26%, -11%)	(-28%, -13%)	(-27%, -12%)
ECD < 750 CELLS/MM²	0 (0%)	1 (3%)	1 (3%)	1 (3%)	1 (3%)	1 (4%)	0 (0%)
ECD < 1000 CELLS/MM²	0 (0%)	1 (3%)	1 (3%)	2 (7%)	1 (3%)	2 (7%)	0 (0%)
N	173	164	165	161	156	152	144
ECD (MEAN, SD)	2501 (366)	1976 (590)	1912 (593)	1868 (579)	1843 (607)	1859 (634)	1773 (609)
95%CI	(2446, 2556)	(1885, 2067)	(1820, 2003)	(1778, 1958)	(1747, 1939)	(1757, 1960)	(1673, 1874)
ECD % CHANGE (MEAN, SD)		-21% (21%)	-24% (21%)	-26% (20%)	-27% (21%)	-26% (23%)	-29% (22%)
95%CI		(-24%, -18%)	(-27%, -20%)	(-29%, -22%)	(-30%, -23%)	(-30%, -22%)	(-33%, -26%)
ECD < 750 CELLS/MM²	0 (0%)	5 (3%)	7 (4%)	8 (5%)	8 (5%)	12 (8%)	12 (8%)
ECD < 1000 CELLS/MM²	0 (0%)	15 (9%)	16 (10%)	14 (9%)	20 (13%)	19 (13%)	19 (13%)

**TABLE 2.A.2
 ENDOTHELIAL CELL DENSITY
 IMT-IMPLANTED EYES
 IMT-002-LTM STUDY**

N	123	116	120	119	119	118	114	70	101	88
ECD (MEAN, SD) 95%CI	2500 (368) (2434, 2566)	1937 (599) (1827, 2047)	1865 (611) (1754, 1975)	1868 (592) (1760, 1976)	1786 (602) (1677, 1895)	1802 (615) (1690, 1915)	1758 (617) (1644, 1873)	1713 (574) (1576, 1850)	1595 (579) (1481, 1709)	1620 (571) (1499, 1741)
ECD % CHANGE (MEAN, SD) 95%CI		-22% (22%) (-26%, -18%)	-25% (22%) (-29%, -21%)	-25% (22%) (-29%, -22%)	-29% (23%) (-33%, -24%)	-28% (23%) (-32%, -24%)	-30% (23%) (-34%, -25%)	-31% (20%) (-36%, -26%)	-36% (22%) (-40%, -32%)	-35% (21%) (-40%, -31%)
ECD < 750 CELLS/MM²	0 (0%)	4 (3%)	8 (7%)	7 (6%)	8 (7%)	11 (9%)	11 (10%)	3 (4%)	9 (9%)	7 (8%)
ECD < 1000 CELLS/MM²	0 (0%)	11 (9%)	14 (12%)	10 (8%)	17 (14%)	15 (13%)	15 (13%)	8 (11%)	21 (21%)	15 (17%)
N	17	15	17	16	16	16	15	9	12	12
ECD (MEAN, SD) 95%CI	2476 (288) (2328, 2625)	1987 (599) (1655, 2319)	1957 (526) (1687, 2227)	2003 (543) (1714, 2293)	1930 (541) (1641, 2218)	1944 (531) (1662, 2227)	1973 (532) (1678, 2267)	1871 (414) (1553, 2189)	1738 (483) (1431, 2045)	1817 (487) (1507, 2126)
ECD % CHANGE (MEAN, SD) 95%CI		-19% (25%) (-33%, -5%)	-20% (21%) (-31%, -9%)	-19% (22%) (-31%, -7%)	-22% (23%) (-34%, -10%)	-21% (22%) (-33%, -10%)	-20% (21%) (-32%, -8%)	-22% (15%) (-33%, -11%)	-29% (21%) (-43%, -16%)	-26% (20%) (-38%, -13%)
ECD < 750 cells/mm²	0 (0%)	1 (7%)	1 (6%)	1 (6%)	1 (6%)	1 (6%)	0 (0%)	0 (0%)	1 (8%)	1 (8%)
ECD < 1000 cells/mm²	0 (0%)	1 (7%)	1 (6%)	1 (6%)	1 (6%)	1 (6%)	0 (0%)	0 (0%)	1 (8%)	1 (8%)
N	106	101	103	103	103	102	99	61	89	76
ECD (MEAN, SD) 95%CI	2504 (380) (2430, 2577)	1929 (602) (1810, 2048)	1850 (625) (1727, 1972)	1847 (599) (1730, 1964)	1764 (611) (1644, 1883)	1780 (626) (1657, 1903)	1726 (624) (1601, 1850)	1690 (593) (1538, 1842)	1576 (591) (1451, 1700)	1589 (580) (1457, 1722)
ECD % CHANGE (MEAN, SD) 95%CI		-23% (22%) (-27%, -19%)	-26% (23%) (-31%, -22%)	-26% (21%) (-31%, -22%)	-30% (23%) (-34%, -25%)	-29% (23%) (-33%, -24%)	-31% (23%) (-36%, -26%)	-33% (21%) (-38%, -27%)	-37% (22%) (-42%, -32%)	-37% (21%) (-42%, -32%)
ECD < 750 CELLS/MM²	0 (0%)	3 (3%)	7 (7%)	6 (6%)	7 (7%)	10 (10%)	11 (11%)	3 (5%)	8 (9%)	6 (8%)
ECD < 1000 CELLS/MM²	0 (0%)	10 (10%)	13 (13%)	9 (9%)	16 (16%)	14 (14%)	15 (15%)	8 (13%)	20 (22%)	14 (18%)

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

a. *The same Table 2 (from most recent email—ECD and % loss over time), but extended out to the end of the longer follow-up group. Please include the following additional information in the table.*

iii) *A comparison at month 24 of the mean ECD for the entire 36 eyes and for the eyes that continued on. (A brief discussion of whether the data from the continuation study appears to be poolable for analysis with the initial study group.)*

Table 2.A.3 displays ECD for the 33 subjects IMT-implanted eyes of subjects enrolled in Protocol IMT-002 who met the criteria of age 65 or greater with no guttata, ACD \geq 3.0 mm and were implanted by a cornea specialist (restricted cohort), as well as the comparison of subjects in this cohort who enrolled in Protocol IMT-002-LTM versus those who did not enroll in IMT-002-LTM.

There was little difference in mean and percent change in ECD for the two cohorts of eyes at 24 months, with a percent change in ECD loss of 20% for subjects that enrolled in the IMT-002-LTM trial as compared to 19% for those not continuing in IMT-002. The 95% confidence intervals were also similar for the two groups. There were no statistically significant between-group differences (Wilcoxon test 0.828 for mean ECD and Wilcoxon test 0.866 for percent change in ECD).

**TABLE 2.A.3
ENDOTHELIAL CELL DENSITY**

**IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS OF AGE WITH NO GUTTATA, ACD ≥ 3.0 MM, IMPLANTED BY CORNEA SPECIALIST
SUBJECTS ENROLLED IN IMT-002-LTM COMPARED TO SUBJECTS NOT ENROLLED IN IMT-002-LTM
IMT-002**

N	33	29	33	29	30	28	27
ECD (MEAN, SD)	2472 (288)	2099 (554)	2063 (497)	2015 (528)	2018 (493)	1983 (522)	1992 (492)
95%CI	(2370, 2574)	(1888, 2310)	(1887, 2239)	(1815, 2216)	(1834, 2202)	(1781, 2186)	(1797, 2187)
ECD % CHANGE (MEAN, SD)		-15% (21%)	-16% (18%)	-18% (20%)	-19% (19%)	-20% (20%)	-19% (19%)
95%CI		(-23%, -7%)	(-23%, -10%)	(-26%, -10%)	(-26%, -11%)	(-28%, -13%)	(-27%, -12%)
ECD < 750 CELLS/MM²	0 (0%)	1 (3%)	1 (3%)	1 (3%)	1 (3%)	1 (4%)	0 (0%)
ECD < 1000 CELLS/MM²	0 (0%)	1 (3%)	1 (3%)	2 (7%)	1 (3%)	2 (7%)	0 (0%)
N	17	15	17	16	16	16	15
ECD (MEAN, SD)	2476 (288)	1987 (599)	1957 (526)	2003 (543)	1930 (541)	1944 (531)	1973 (532)
95%CI	(2328, 2625)	(1655, 2319)	(1687, 2227)	(1714, 2293)	(1641, 2218)	(1662, 2227)	(1678, 2267)
ECD % CHANGE (MEAN, SD)		-19% (25%)	-20% (21%)	-19% (22%)	-22% (23%)	-21% (22%)	-20% (21%)
95%CI		(-33%, -5%)	(-31%, -9%)	(-31%, -7%)	(-34%, -10%)	(-33%, -10%)	(-32%, -8%)
ECD < 750 CELLS/MM²	0 (0%)	1 (7%)	1 (6%)	1 (6%)	1 (6%)	1 (6%)	0 (0%)
ECD < 1000 CELLS/MM²	0 (0%)	1 (7%)	1 (6%)	1 (6%)	1 (6%)	1 (6%)	0 (0%)
N	16	14	16	13	14	12	12
ECD (MEAN, SD)	2468 (297)	2219 (494)	2176 (454)	2030 (531)	2120 (428)	2036 (527)	2016 (460)
95%CI	(2310, 2626)	(1933, 2504)	(1934, 2417)	(1709, 2351)	(1873, 2367)	(1701, 2371)	(1723, 2308)
ECD % CHANGE (MEAN, SD)		-10% (15%)	-12% (13%)	-17% (19%)	-15% (14%)	-19% (17%)	-19% (15%)
95%CI		(-18%, -1%)	(-19%, -5%)	(-29%, -6%)	(-23%, -7%)	(-30%, -9%)	(-28%, -9%)
ECD < 750 CELLS/MM²	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
ECD < 1000 CELLS/MM²	0 (0%)	0 (0%)	0 (0%)	1 (8%)	0 (0%)	1 (8%)	0 (0%)
WILCOXON TEST FOR ECD							0.828
WILCOXON TEST FOR ECD % CHANGE							0.866

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

b. Percent of enrolled eyes with mean ECD (6 months to 24 months postop) below 1000 cells/mm² and below 750 cells per mm² along with upper confidence limit of the percents.

Table 2.B.1.1 and Table 2.B.1.2 present within-eye mean ECD for the period 6 to 24 months and the predicted percent of eyes with a within-eye mean ECD of <1000 cells/mm² and <750 cells/mm², respectively, for subjects in the IMT-002 study. Data for three cohorts are presented, as follows:

- IMT-implanted eyes
- Cohort A, consisting of eyes of subjects age \geq 65, with no guttata, with ACD \geq 3.0 mm, and implanted by cornea specialist (restricted cohort); and
- Cohort B, consisting of the IMT-implanted eyes excluded from Cohort A.

The mean of the within-eye ECD for Cohort A, the restricted cohort, was higher at 2017 cells/mm² than the mean of the within-eye ECD for the IMT-implanted eyes (1869 cells/mm²) and for Cohort B, the eyes excluded from the restricted cohort (1839 cells/mm²).

The number and percent of eyes with within-eye mean ECD of <1000 and <750 cells/mm² was lowest in the restricted cohort with a single eye (3.0%) in this category. In contrast, 22 of the IMT-implanted eyes (10.9%) and 21 of the Cohort B eyes (12.5%) had mean ECD <1000 cells/mm². The incidence of eyes with ECD <750 cells/mm² was 5.0% of the IMT-implanted eyes and 5.4% of Cohort B.

TABLE 2.B.1.1
WITHIN-EYE MEAN ECD FOR 6 TO 24 MONTHS
PREDICTED PROBABILITY OF ECD < 1000 CELLS/MM²
IMT-IMPLANTED EYES
IMT-002 STUDY

IMT-IMPLANTED EYES	201	1868.5 (577.3)	22	10.9%	(7.0%, 16.1%)
COHORT A IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS, WITH NO GUTTATA, ACD ≥ 3.0 MM AND IMPLANTED BY A CORNEA SPECIALIST	33	2017.0 (492.0)	1	3.0%	(0.1%, 15.8%)
COHORT B IMT-IMPLANTED EYES EXCLUDED FROM COHORT A	168	1839.4 (589.5)	21	12.5%	(7.9%, 18.5%)

¹Exact confidence interval per Clopper-Pearson method

TABLE 2.B.1.2
WITHIN-EYE MEAN ECD FOR 6 TO 24 MONTHS
PREDICTED PROBABILITY OF ECD < 750 CELLS/MM²
IMT-IMPLANTED EYES
IMT-002 STUDY

IMT-IMPLANTED EYES	201	1868.5 (577.3)	10	5.0%	(2.4%, 9.0%)
COHORT A IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS, WITH NO GUTTATA, ACD ≥ 3.0 MM AND IMPLANTED BY A CORNEA SPECIALIST	33	2017.0 (492.0)	1	3.0%	(0.1%, 15.8%)
COHORT B IMT-IMPLANTED EYES EXCLUDED FROM COHORT A	168	1839.4 (589.5)	9	5.4%	(2.5%, 9.9%)

¹Exact confidence interval per Clopper-Pearson method

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

c. A brief analysis of the number of eyes with decompensation or late corneal edema that were in this group (guttata-free, deep ACD, & cornea-trained surgeons).

As shown in Table 2.C, at 24 months in the IMT-002 study, none of the eyes in the restricted cohort (Cohort A, with age 65 or older, with no guttata, ACD \geq 3.0 mm, implanted by cornea specialists) presented with late corneal edema or corneal decompensation. In the eyes that did not meet the restricted criteria, the incidence of corneal edema was 3.3% and 1.1% of these eyes had corneal decompensation.

In the IMT-002-LTM study at 48 months there were 2 reports (11.8%) of late corneal edema and 1 report (5.9%) of corneal decompensation in the restricted cohort. For the non-restricted cohort of eyes, late corneal edema was reported in 11 eyes (9.8%), and 3 eyes (2.7%) presented with corneal decompensation.

TABLE 2.C
INCIDENCE OF LATE CORNEAL EDEMA AND/OR CORNEAL DECOMPENSATION
IMT-002 AND IMT-002-LTM STUDIES

ENROLLED (N)	217	217
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	6 (2.8%)	2 (0.9%)
COHORT A		
IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS WITH NO GUTTATA, ACD ≥ 3.0 MM AND OPERATED BY CORNEA SPECIALIST (N)	33	33
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	<i>0 (0.0%)</i>	<i>0 (0.0%)</i>
COHORT B		
SUBJECTS EXCLUDED FROM COHORT A (N)	184	184
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	<i>6 (3.3%)</i>	<i>2 (1.1%)</i>
ENROLLED (N)	129	129
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	13 (10.1%)	4 (3.1%)
COHORT A		
IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS WITH NO GUTTATA, ACD ≥ 3.0 MM AND OPERATED BY CORNEA SPECIALIST (N)	17	17
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	<i>2 (11.8%)</i>	<i>1 (5.9%)</i>
COHORT B		
SUBJECTS EXCLUDED FROM COHORT A (N)	112	112
REPORTED EVENTS (N) AND PERCENT (%) OF ENROLLED	<i>11 (9.8%)</i>	<i>3 (2.7%)</i>

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

d. A biexponential analysis including estimation of parameters and confidence limits on these estimates. (If unable to perform this analysis, please provide justification.)

Tables 2.D.1, 2.D.2, and 2.D.3 present predicted ECD annual percent loss and related information based on a biexponential model utilizing data from baseline to 48 months for the at risk cohort of subjects (age \geq 65, with no guttata, with ACD \geq 3.0 mm, and implanted by a cornea specialist). The predicted annual ECD loss for this cohort of subjects is 3.4% with a 95% confidence level of 0.3%, 6.4%.

This prediction is highly consistent with the predicted annual ECD loss of 3.8% (95% C.I. 2.0%, 5.5%) for the cohort of non-guttata eyes with ACD \geq 3.0 mm based on data from baseline to 48 months presented in Table 21.1 of A014, submitted to FDA in September 2008. For the cohort of IMT-implanted eyes (i.e., a non-restricted cohort), the predicted annual ECD loss was 4.8% (95% C.I. 3.4%, 6.2%) based on data from baseline to 48 months; this was submitted in Table 22.1 of A014.

TABLE 2.D.1
BI-EXPONENTIAL MODEL FOR ECD
 $ECD_{month} = p \times e^{-a \times month} + q \times e^{-b \times month} + \epsilon$
IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS WITH NO GUTTATA, $ACD \geq 3.0$ MM AND
OPERATED BY CORNEA SPECIALIST
BASED ON DATA FROM BASELINE TO 48 MONTHS

p	399.9	111.5	180.3	619.5	3.6	<.001
a	0.6	0.5	-0.5	1.6	1.1	0.270
q	2074.2	76.1	1924.3	2224.1	27.3	<.001
b	0.003	0.002	-0.000	0.006	1.8	0.069

Annual ECD % Loss (90% CI) based on the slow exponential rate: 3.4% (0.3%, 6.4%).

TABLE 2.D.2
PREDICTED MEAN ECD BASED ON BI-EXPONENTIAL MODEL FOR
IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS WITH NO GUTTATA, $ACD \geq 3.0$ MM AND BY
OPERATED BY CORNEA SPECIALIST
BASED ON DATA FROM BASELINE TO 48 MONTHS

3 Months	2125.4	1987.8, 2263.0
12 Months	2004.0	1930.3, 2077.8
24 Months	1935.5	1868.8, 2002.2
36 Months	1869.7	1769.4, 1970.0
48 Months	1806.1	1660.4, 1951.9
54 Months	1775.2	1606.2, 1944.1
60 Months	1744.7	1552.9, 1936.6

TABLE 2.D.3
PREDICTED PROBABILITY OF ECD LESS THAN THRESHOLD BASED ON
BI-EXPONENTIAL MODEL FOR
IMT-IMPLANTED EYES OF SUBJECTS ≥ 65 YEARS WITH NO GUTTATA, ACD ≥ 3.0 MM AND
OPERATED BY CORNEA SPECIALIST
BASED ON DATA FROM BASELINE TO 48 MONTHS
(EXCLUDING PREOP RESIDUALS)

3 MONTHS	3.8	2.4	2.4	2.4	2.4	2.4	1.9
12 MONTHS	4.3	2.9	2.9	2.4	2.4	2.4	2.4
24 MONTHS	4.8	2.9	2.9	2.9	2.9	2.4	2.4
36 MONTHS	5.3	3.8	3.3	2.9	2.9	2.9	2.4
48 MONTHS	5.7	3.8	3.8	3.3	2.9	2.9	2.9
54 MONTHS	5.7	4.3	3.8	3.8	3.3	2.9	2.9
60 MONTHS	5.7	4.3	4.3	3.8	3.8	2.9	2.9

The empirical frequency of residuals was used to estimate these probabilities.

2. *Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):*

e. The number of cornea specialists in the study.

f. The number of enrolled eyes (both phases of the study) by site for the cornea specialist/non guttata/large ACD group.

Table 2.E-F presents the number of cornea specialists (10) who participated in the IMT-002 study and their affiliation with 10 of the IMT-002 investigation sites. This table also presents the number of operated eyes and the number of eyes in the restricted cohort of subjects with age \geq 65, no guttata, ACD \geq 3.0 mm, and implanted by cornea specialists for subjects in the IMT-002 study and those who continued in the IMT-002-LTM study.

TABLE 2.E-F
ENROLLMENT AT CORNEA SPECIALIST SITES
IMT-002 AND IMT-002-LTM STUDIES

001 - Associated Eye Care, Dr. Lane	13	6	11	5
004 - Fine, Hoffman & Packer, Dr. Hoffmann	3	2	2	1
008 - Retina Group of Washington, Dr. Martin	2	1	0	0
009 - Manhattan Eye & Ear, Dr. Mandelbaum	2	1	1	0
010 - OCB Boston, Dr. Raizman	9	5	2	1
011 - Massachusetts Eye & Ear, Dr. Colby	4	2	2	0
014 - Emory Eye Center, Dr. Stulting	15	11	11	9
021 - Medical College of Wisconsin Eye Inst., Dr. Koenig	2	2	0	0
025 - Doheny Retina Inst., Dr. Irvine	5	1	2	0
031 - Duke University Eye Center, Dr. Kim	6	2	3	1
Total Number of Sites = 10, Total Number of Cornea Specialists = 10	61	33	34	17

2. Please provide the following analyses for the restricted cohort (non-guttata eyes, 65 or older, ACD \geq 3.0mm, cornea-trained specialist):

g. Patient accountability for this group.

Tables 2.G.1 and 2.G.2 present the requested accountability information for the cohort of subjects \geq 65 years of age, with no guttata, ACD \geq 3.0 mm² and operated by cornea specialists.

**TABLE 2.G.1
ACCOUNTABILITY
IMT-IMPLANTED EYES
 \geq 65 YEARS OF AGE, NON-GUTTATA, ACD \geq 3.0 MM, CORNEA SPECIALIST
IMT-002 STUDY**

AVAILABLE FOR ANALYSIS	N/N (%)	33/33 (100.0%)	32/33 (97.0%)	33/33 (100.0%)	30/33 (90.9%)	31/33 (93.9%)	29/33 (87.9%)	27/33 (81.8%)
DISCONTINUED	N/N (%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	2/33 (6.1%)
DECEASED	N/N (%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	1/33 (3.0%)
IMT REMOVED	N/N (%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	1/33 (3.0%)
LOST TO FOLLOW-UP	N/N (%)	0/33 (0.0%)	0/33 (0.0%)	0/33 (0.0%)	1/33 (3.0%)	2/33 (6.1%)	3/33 (9.1%)	3/33 (9.1%)
MISSED VISIT	N/N (%)	0/33 (0.0%)	1/33 (3.0%)	0/33 (0.0%)	2/33 (6.1%)	0/33 (0.0%)	1/33 (3.0%)	1/33 (3.0%)
% ACCOUNTABILITY = AVAILABLE FOR ANALYSIS \div (ENROLLED - DISCONTINUED - NOT YET ELIGIBLE)		33/33 (100.0%)	32/33 (97.0%)	33/33 (100.0%)	30/33 (90.9%)	31/33 (93.9%)	29/33 (87.9%)	27/31 (87.1%)

TABLE 2.G.2
ACCOUNTABILITY
IMT-IMPLANTED EYES
≥ 65 YEARS OF AGE, NON-GUTTATA, ACD ≥ 3.0 MM, CORNEA SPECIALIST
IMT-002-LTM STUDY

AVAILABLE FOR ANALYSIS	N/N (%)	0/0	10/11 (90.9%)	14/17 (82.4%)	13/17 (76.5%)
DISCONTINUED	N/N (%)		1/11 (9.1%)	2/17 (11.8%)	2/17 (11.8%)
DECEASED	N/N (%)		0/11 (0.0%)	1/17 (5.9%)	1/17 (5.9%)
IMT REMOVED	N/N (%)		1/11(9.1%)	1/17 (5.9%)	1/17 (5.9%)
LOST TO FOLLOW-UP	N/N (%)		0/11 (0.0%)	0/17 (0.0%)	2/17 (11.8%)
MISSED VISIT	N/N (%)		0/11 (0.0%)	1/17 (5.9%)	0/17 (0.0%)
% ACCOUNTABILITY = AVAILABLE FOR ANALYSIS ÷ (ENROLLED - DISCONTINUED - NOT YET ELIGIBLE)			10/11 (90.9%)	14/15 (93.3%)	13/15 (86.7%)

ADDITIONAL ANALYSES

Three additional summary tables are provided in this section. The primary effectiveness endpoint as well as the proportion of eyes with gains in BCDVA of ≥ 2 lines and of ≥ 3 lines are displayed in Table 3. Acute endothelial cell loss is presented in Table 4 and ECD loss beyond the acute phase is shown in Table 5.

Table 3 presents the primary effectiveness endpoint, i.e., ≥ 2 lines gain of BCDVA or BCNVA achieved by $\geq 50\%$ of the study population at 12 months for the following cohorts of eyes:

- Operated eyes
- IMT-implanted eyes
- Cohort A, consisting of eyes of subjects age ≥ 65 , with no guttata, with ACD ≥ 3.0 mm, and implanted by cornea specialist (restricted cohort); and
- Cohort B, consisting of the IMT-implanted eyes excluded from Cohort A.

Additionally, the number and percent of subject achieving ≥ 2 lines gain of BCDVA or BCNVA, as well as those who achieved a gain in BCDVA of ≥ 2 lines and ≥ 3 lines in the IMT-002 study is presented at 12 and 24 months (Table 3).

The visual acuity endpoint was achieved for all cohorts of eyes, and the percent of subjects with 2 and 3 lines of improvement in BCDVA were consistent across the cohorts at both 12 and 24 months.

TABLE 3
EFFECTIVENESS ENDPOINTS
PRIMARY ENDPOINT AND PROPORTION OF EYES WITH GAIN OF ≥ 2 OR ≥ 3 LINES BCDVA
IMT-002 STUDY

EFFECTIVENESS, N=	194	192	31	161	175	173	27	146
PRIMARY EFFECTIVENESS ENDPOINT: ≥ 2 LINES GAIN OF BCDVA OR BCNVA N (%), 95%CI	171 (88.1%) 83.6%, 91.8%	173 (90.1%) 85.8%, 93.4%	29 (93.5%) 81.1%, 98.8%	144 (89.4%) 84.6%, 93.2%	150 (85.7%) 80.6%, 89.9%	149 (86.1%) 81.0%, 90.2%	25 (92.6%) 78.5%, 98.7%	124 (84.9%) 79.2%, 89.6%
≥ 2 LINES GAIN OF BCDVA AND BCNVA N (%), 95%CI	141 (72.7%) 66.9%, 77.9%	141 (73.4%) 67.7%, 78.6%	24 (77.4%) 61.7%, 88.9%	117 (72.7%) 66.3%, 78.4%	115 (65.7%) 59.4%, 71.7%	114 (65.9%) 59.5%, 71.9%	19 (70.4%) 52.9%, 84.3%	95 (65.1%) 58.0%, 71.6%
BCDVA, N=	194	193	31	162	175	173	27	146
BCDVA INCREASED ≥ 2 LINES N (%), 95%CI	154 (79.4%) 74.0%, 84.1%	155 (80.3%) 75.0%, 84.9%	27 (87.1%) 72.9%, 95.5%	128 (79.0%) 73.1%, 84.2%	130 (74.3%) 68.3%, 79.7%	129 (74.6%) 68.5%, 80.0%	20 (74.1%) 56.8%, 87.1%	109 (74.7%) 68.0%, 80.5%
BCDVA INCREASED ≥ 3 LINES N (%), 95%CI	128 (66.0%) 60.0%, 71.6%	128 (66.3%) 60.3%, 72.0%	21 (67.7%) 51.5%, 81.3%	107 (66.0%) 59.4%, 72.2%	103 (58.9%) 52.4%, 65.1%	103 (59.5%) 53.0%, 65.8%	16 (59.3%) 41.7%, 75.2%	87 (59.6%) 52.5%, 66.4%

Mean ECD and percent loss in ECD at 6 months are presented in Table 4 for the following cohorts of eyes:

- IMT-implanted eyes;
- Non-guttata IMT-implanted eyes;
- Non-guttata IMT-implanted eyes with $ACD \geq 3.0$ mm; and
- IMT-implanted subjects age ≥ 65 , with no guttata eyes, with $ACD \geq 3.0$ mm, with surgery performed by a cornea specialist.

Information on the eyes that are excluded from each of these cohorts are also presented in Table 4. As shown, the percent loss in ECD is lower in the restricted, i.e., risk-reduced groups than in the non-restricted cohorts of eyes. This finding is anticipated, and consistent with the objective of restricting implantation of the IMT in eyes with established risk factors (guttata, $ACD < 3.0$ mm).

TABLE 4
MEAN ECD AND ECD % LOSS AT BASELINE AND 6 MONTHS POSTOPERATIVE VISIT
IMT-IMPLANTED EYES AND RISK REDUCED COHORTS
IMT-002 STUDY

N	206	198	180	172	112	107	33	33
ECD (MEAN)	2496	1937	2507	1970	2534	2046	2472	2063
95%CI	(2447, 2545)	(1856, 2018)	(2457, 2557)	(1884, 2056)	(2473, 2596)	(1945, 2146)	(2370, 2574)	(1887, 2239)
ECD % LOSS (MEAN)		22.4%		21.4%		19.0%		16.2%
95%CI		(19.4%, 25.3%)		(18.3%, 24.5%)		(15.3%, 22.7%)		(9.7%, 22.6%)
N			26	26	94	91	173	165
ECD (MEAN)			2419	1719	2451	1809	2501	1912
95%CI			(2242, 2596)	(1476, 1963)	(2373, 2528)	(1680, 1937)	(2446, 2556)	(1820, 2003)
ECD % LOSS (MEAN)				28.8%		26.4%		23.6%
95%CI				(19.8%, 37.7%)		(21.8%, 30.9%)		(20.3%, 26.9%)

Table 5 presents mean ECD, mean percent ECD loss and annual percent ECD loss for the cohort of IMT-implanted eyes; non-guttata IMT-implanted eyes; non-guttata IMT-implanted eyes with ACD ≥ 3.0 mm; and non-guttata IMT-implanted eyes, age ≥ 65 , with ACD ≥ 3.0 mm, implanted by cornea specialist (fully restricted cohort). Annual percent ECD loss is provided for the periods 6 to 24 months, 12 to 24 months, 24 to 48 months, 6 to 48 months, 24 to 48 months and 36 to 48 months. The annual percent loss in ECD for the period 6 to 48 months was approximately 3.4% for all cohorts except for the fully restricted cohort, which had an annual loss of 2.7%. The annual ECD % loss for the period 24 to 48 months was approximately 3% for all cohorts except for the fully restricted cohort, which had an annual loss of 1% per year. These annual rates of ECD loss for IMT-implanted eyes and the other cohorts are generally stable and consistent with the annual rate of ECD loss of 2.8% reported by Bourne and colleagues (1994) for extracapsular cataract extraction and IOL implantation. The annual rate of ECD loss does not accelerate over time for any of the cohorts.

TABLE 5
MEAN ECD, ECD % LOSS FROM BASELINE, ANNUAL ECD % LOSS
IMT-IMPLANTED EYES AND RISK REDUCED COHORTS
IMT-002 AND IMT-002-LTM STUDIES

N	198	171	172	150	107	95	33	27
ECD (MEAN)	1937	1808	1970	1848	2046	1907	2063	1992
95%CI	(1856, 2018)	(1718, 1898)	(1884, 2056)	(1753, 1942)	(1945, 2146)	(1795, 2019)	(1887, 2239)	(1797, 2187)
ECD % LOSS (MEAN)	22.4%	27.7%	21.4%	26.5%	19.0%	25.0%	16.2%	19.4%
95%CI	(19.4%, 25.3%)	(24.4%, 31.0%)	(18.3%, 24.5%)	(23.0%, 29.9%)	(15.3%, 22.7%)	(21.0%, 29.1%)	(9.7%, 22.6%)	(12.0%, 26.7%)
ANNUAL % ECD LOSS 6 TO 24 MONTHS,								
N		168		147		94		27
MEAN		5.4%		5.3%		5.1%		3.1%
95%CI		(3.2%, 7.6%)		(3.0%, 7.7%)		(2.4%, 7.8%)		(-2.0%, 8.2%)
N	186	171	162	150	103	95	30	27
ECD (MEAN)	1871	1808	1904	1848	1935	1907	2018	1992
95%CI	(1786, 1957)	(1718, 1898)	(1815, 1993)	(1753, 1942)	(1831, 2039)	(1795, 2019)	(1834, 2202)	(1797, 2187)
ECD % LOSS (MEAN)	25.3%	27.7%	24.3%	26.5%	23.6%	25.0%	18.5%	19.4%
95%CI	(22.2%, 28.4%)	(24.4%, 31.0%)	(21.1%, 27.5%)	(23.0%, 29.9%)	(19.7%, 27.5%)	(21.0%, 29.1%)	(11.4%, 25.7%)	(12.0%, 26.7%)
ANNUAL % ECD LOSS 12 TO 24 MONTHS,								
N		169		148		94		26
MEAN		2.2%		2.3%		1.5%		3.6%
95%CI		(-1.0%, 5.5%)		(-1.3%, 5.9%)		(-3.0%, 6.0%)		(-4.3%, 11.5%)

TABLE 5 (CONTINUED)
MEAN ECD, ECD % LOSS FROM BASELINE, ANNUAL ECD % LOSS
IMT-IMPLANTED EYES AND RISK REDUCED COHORTS
IMT-002 AND IMT-002-LTM STUDIES

N	198	88	172	76	107	45	33	12
ECD (MEAN)	1937	1620	1970	1670	2046	1704	2063	1817
95%CI	(1856, 2018)	(1499, 1741)	(1884, 2056)	(1542, 1798)	(1945, 2146)	(1544, 1864)	(1887, 2239)	(1507, 2126)
ECD % LOSS (MEAN)	22.4%	35.4%	21.4%	34.1%	19.0%	33.3%	16.2%	25.6%
95%CI	(19.4%, 25.3%)	(31.0%, 39.8%)	(18.3%, 24.5%)	(29.4%, 38.8%)	(15.3%, 22.7%)	(27.2%, 39.4%)	(9.7%, 22.6%)	(13.1%, 38.1%)
ANNUAL % ECD LOSS 6 TO 48 MONTHS								
N		85		73		44		12
MEAN		3.4%		3.3%		3.6%		2.7%
95%CI		(2.1%, 4.7%)		(1.9%, 4.7%)		(1.9%, 5.2%)		(-1.2%, 6.5%)
N	171	88	150	76	95	45	27	12
ECD (MEAN)	1808	1620	1848	1670	1907	1704	1992	1817
95%CI	(1718, 1898)	(1499, 1741)	(1753, 1942)	(1542, 1798)	(1795, 2019)	(1544, 1864)	(1797, 2187)	(1507, 2126)
ECD % LOSS (MEAN)	27.7%	35.4%	26.5%	34.1%	25.0%	33.3%	19.4%	25.6%
95%CI	(24.4%, 31.0%)	(31.0%, 39.8%)	(23.0%, 29.9%)	(29.4%, 38.8%)	(21.0%, 29.1%)	(27.2%, 39.4%)	(12.0%, 26.7%)	(13.1%, 38.1%)
ANNUAL % ECD LOSS 24 TO 48 MONTHS								
N		86		74		44		12
MEAN		2.8%		2.6%		3.5%		0.8%
95%CI		(1.0%, 4.6%)		(0.6%, 4.6%)		(1.1%, 5.9%)		(-5.8%, 7.3%)
N	70	88	63	76	36	45	9	12
ECD (MEAN)	1713	1620	1728	1670	1843	1704	1871	1817
95%CI	(1576, 1850)	(1499, 1741)	(1580, 1875)	(1542, 1798)	(1659, 2027)	(1544, 1864)	(1553, 2189)	(1507, 2126)
ECD % LOSS (MEAN)	31.2%	35.4%	30.9%	34.1%	28.4%	33.3%	21.9%	25.6%
95%CI	(26.3%, 36.0%)	(31.0%, 39.8%)	(25.6%, 36.1%)	(29.4%, 38.8%)	(21.7%, 35.0%)	(27.2%, 39.4%)	(10.7%, 33.2%)	(13.1%, 38.1%)
ANNUAL % ECD LOSS 36 TO 48 MONTHS,								
N		51		47		27		6
MEAN		2.8%		2.5%		3.2%		-2.6%
95%CI		(-1.4%, 7.0%)		(-2.0%, 6.9%)		(-2.9%, 9.2%)		(-7.6%, 2.5%)