	n	201	250	0.65, 0.94	64	67	0.61, 1.21	265	317	0.68, 0.94
	%	8.42	10.64		9.65	11.20		8.69	10.76	
Troponin over ULN at baseline =yes										
Yes	N	1347	1373	0.92	456	455	0.53	1803	1828	0.80
	n	134	148	0.73, 1.16	34	62	0.35, 0.80	168	210	0.65, 0.98
	%	9.95	10.78		7.46	13.63		9.32	11.49	
No	N	2191	2188	0.82	408	424	0.77	2599	2612	0.81
	n	204	246	0.68, 0.99	41	54	0.52, 1.16	245	300	0.69, 0.96
	%	9.31	11.24		10.05	12.74		9.43	11.49	
Troponin over ULN at baseline =no										
Yes	N	275	256	0.46	261	300	1.08	536	556	0.72
	n	20	39	0.27, 0.79	31	33	0.66, 1.77	51	72	0.51, 1.04
	%	7.27	15.23		11.88	11.00		9.52	12.95	
No	N	623	587	0.75	219	181	1.25	842	768	0.88
	n	56	68	0.53, 1.07	22	15	0.65. 2.4	78	83	0.62, 1.26
	%	8.99	11.58		10.05	8.29		9.26	10.81	
Troponin over ULN at baseline =yes and Sex=female										
Yes	N	324	366	1.03	105	110	0.37	429	476	0.79
	n	32	35	0.63, 1.66	7	18	0.16, 0.90	39	53	0.52, 1.20
	%	9.88	9.56		6.67	16.36		9.09	11.13	
No	N	562	589	0.99	69	119	1.79	631	708	1.07
	n	63	67	0.70, 1.40	10	10	0.75, 4.31	73	77	0.78, 1.48
	%	11.21	11.38		14.49	8.40		11.57	10.88	
Troponin over ULN at baseline =no and Sex=female										
Yes	N	68	77	0.68	41	54	1.33	109	131	0.91
	n	6	10	0.24, 1.87	6	6	0.43, 1.13	12	16	0.43, 1.92
	%	8.82	12.99		14.63	11.11		11.01	12.21	
No	N	185	176	0.93	57	44	0.65	242	220	0.86
	n	21	21	0.51, 1.71	6	7	0.22, 1.93	27	28	0.51, 1.45
	%	11.35	11.93		10.53	15.91		11.16	12.73	
Troponin over ULN at baseline =yes and Sex=male										
Yes	N	1023	1007	0.89	351	345	0.59	1374	1352	0.80
	n	102	103	0.68, 1.16	27	44	0.36, 0.95	129	157	0.64, 1.01
	%	9.97	10.23		7.69	12.75		9.39	11.61	
No	N	1629	1599	0.77	339	305	0.61	1968	1904	0.73
	n	141	179	0.61, 0.95	31	44	0.39, 0.97	172	223	0.60, 0.90
	%	8.66	11.19		9.15	14.43		8.74	11.71	
Troponin over ULN at baseline =no and Sex=male										
Yes	N	207	179	0.40	220	246	1.03	427	425	0.68
	n	14	29	0.21, 0.76	25	27	0.6, 0.78	39	56	0.45, 1.02
	%	6.76	16.20		11.36	10.98		9.13	13.18	
No	N	438	411	0.68	162	137	1.76	600	548	0.84
	n	35	47	0.44, 1.05	16	8	0.75, 4.12	51	55	0.57, 1.22
	%	8.00	11.44		9.88	5.84		8.50	10.04	

Table 3 Subgroup Analysis:
Use of GPIIb/IIIa Inhibitors up to cath lab

	UA/NSTEMI			STEMI			All ACS		
	Prasugrel (N=5044)	Clopidogrel (N=5030)	HR 95% CI	Prasugrel (N=1769)	Clopidogrel (N=1765)	HR 95% CI	Prasugrel (N=6813)	Clopidogrel (N=6795)	HR 95% CI

Yes	N	366	353	0.85	171	199	0.69	537	552	0.80
	n	37	42	0.54, 1.31	14	23	0.36, 0.34	51	65	0.55, 1.15
	%	10.11	11.90		8.19	11.56		9.50	11.78	
No	N	4678	4677	0.82	1598	1566	0.80	6276	6243	0.81
	n	435	523	0.72, 0.93	160	193	0.65, 0.99	592	716	0.73, 0.91
	%	9.23	11.18		10.01	12.32		9.43	11.47	
Female										
Yes	N	84	92	1.13	33	48	0.33	117	140	0.80
	n	10	10	0.47, 2.70	2	8	0.07, 1.57	12	18	0.38, 1.65
	%	11.90	10.87		6.06	16.67		10.26	12.86	
No	N	1241	1307	0.89	347	371	0.86	1588	1678	0.88
	n	127	149	0.70, 1.13	39	48	0.56, 1.31	166	197	0.72, 1.09
	%	10.23	11.40		11.24	12.94		10.45	11.74	
Male										
Yes	N	282	261	0.77	138	151	0.86	420	412	0.80
	n	27	32	0.46, 1.28	12	15	0.41, 1.85	39	47	0.53, 1.23
	%	9.57	12.26		8.70	9.93		9.29	11.41	
No	N	3437	3370	0.79	1251	1195	0.79	4688	4565	0.79
	n	305	374	0.68, 0.92	121	145	0.62, 1.0	426	519	0.70, 0.90
	%	8.87	11.10		9.67	12.13		9.09	11.37	
Troponin over ULN at baseline =yes										
Yes	N	285	268	0.94	68	86	0.84	353	354	0.92
	n	32	32	0.58, 1.54	7	10	0.32, 2.21	39	42	0.60, 1.43
	%	11.23	11.94		10.29	11.63		11.05	11.86	
No	N	3256	3293	0.85	796	793	0.62	4049	4086	0.90
	n	306	362	0.73, 0.99	68	106	0.46, 0.84	374	468	0.70, 0.91
	%	9.40	11.00		8.54	13.37		9.24	11.45	
Troponin over ULN at baseline =no										
Yes	N	51	49	0.47	54	62	0.49	105	111	0.48
	n	3	6	0.12, 1.88	3	7	0.13, 1.90	6	13	0.18, 1.26
	%	5.88	12.24		5.56	11.29		5.71	11.71	
No	N	847	794	0.66	426	419	1.22	1273	1213	0.88
	n	73	101	0.49, 0.89	50	41	0.81, 1.84	123	142	0.64, 1.04
	%	8.62	12.72		11.74	9.79		9.66	11.71	
Troponin over ULN at baseline =yes and Sex=female										
Yes	N	58	62	1.21	17	20	-	75	82	0.87
	n	9	8	0.47, 3.14	0	3		9	11	0.36, 2.09
	%	15.52	12.90		-	15.00		12.00	13.42	
No	N	828	893	0.99	157	209	0.89	985	1102	0.97
	n	86	94	0.74, 1.33	17	25	0.48, 1.65	103	119	0.75, 1.26
	%	10.39	10.53		10.83	11.96		10.46	10.80	
Troponin over ULN at baseline =no and Sex=female										
Yes	N	17	16	-	6	12	-	23	28	0.74
	n	1	0		0	2		1	2	0.07, 8.46
	%	5.88	-		-	16.67		4.35	7.14	
No	N	236	237	0.82	92	86	1.02	328	323	0.88
	n	26	31	0.49, 1.39	12	11	0.45, 2.31	38	42	0.56, 1.36
	%	11.02	13.08		13.04	12.79		11.59	13.00	
Troponin over ULN at baseline =yes and Sex=male										
Yes	N	227	206	0.87	51	66	1.25	278	272	0.95
	n	23	24	0.49, 1.54	7	7	0.44, 3.57	30	31	0.57, 1.56
	%	10.13	11.65		13.73	10.61		10.79	11.40	
No	N	2425	2400	0.81	639	584	0.56	3064	2984	0.75

	n	220	268	0.67, 0.96	51	81	0.39, 0.79	271	349	0.64, 0.87
	%	9.07	11.17		7.98	13.87		8.85	11.70	
Troponin over ULN at baseline =no and Sex=male										
Yes	N	34	33	0.29	48	50	0.63	82	83	0.43
	n	2	6	0.06, 1.43	3	5	0.15, 2.62	5	11	0.15, 1.25
	%	5.88	18.18		6.25	10.00		6.10	13.25	
No	N	611	557	0.59	334	333	1.29	945	890	0.79
	n	47	70	0.41, 0.86	38	30	0.80, 2.07	85	100	0.59, 1.05
	%	7.69	12.57		11.38	9.01		8.99	11.24	

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/s/

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6/17/2008 03:43:48 PM
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

STATISTICAL REVIEW AND EVALUATION

GENOMICS STUDIES

NDA/Serial Number:	22-307 / S_000
Drug Name:	EFFIENT™ (prasugrel hydrochloride) Tablets
Indication(s):	Treatment of subjects with acute coronary syndromes (ACS)
Applicant:	Eli Lilly
Date(s):	Date of Document: December, 26 2007 PDUFA Due Date: June 26, 2008
Review Priority:	Priority
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Table of Contents

1. EXECUTIVE SUMMARY ..... - 5 -

1.1 CONCLUSIONS AND RECOMMENDATIONS ..... - 5 -
1.2 BRIEF OVERVIEW OF GENOMIC STUDIES ..... - 5 -
1.3 STATISTICAL ISSUES AND FINDINGS ..... - 5 -

2. INTRODUCTION ..... - 5 -

2.1 OVERVIEW ..... - 5 -
2.2 STATISTICAL METHODOLOGY ..... - 6 -
2.3 DATA SOURCES ..... - 6 -

3. STATISTICAL EVALUATION ..... - 6 -

3.1 EVALUATION OF EFFICACY ..... - 6 -
3.1.1 Patient Disposition, Demographic and Baseline Characteristics ..... - 6 -
3.1.2 Sponsor's Analysis Results ..... - 11 -
3.1.3 Reviewer's Analysis Results ..... - 15 -

4. SUMMARY AND CONCLUSIONS ..... - 20 -

4.1 STATISTICAL ISSUES AND COLLECTIVE EVIDENCE ..... - 20 -
4.2 CONCLUSIONS AND RECOMMENDATIONS ..... - 21 -

List of Tables

Table 1 Patient Disposition, Demographic and Baseline Characteristics, Genetics Population ..... - 6 -
Table 2 Demographic and Baseline Characteristics, ITT population ..... - 9 -
Table 3 Number and Percentage of Subjects Reaching the Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke from Randomization through Study End: Prasugrel 2C19/2C9 EMfgs versus RMfgs ..... - 11 -
Table 4 Number and Percentage of Subjects Reaching the Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke from Randomization through Study End: Clopidogrel 2C19/2C9 EMfgs versus RMfgs ..... - 14 -
Table 5 Number and Percentage of Subjects Having Genetics Information and Reaching the Composite Endpoint from Randomization through Study End –CEC Adjudicated ..... - 16 -
Table 6 Number and Percentage of Subjects Reaching the Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke—CEC Adjudicated (ITT) ..... - 16 -
Table 7 Number and Percentage of Subjects Reaching the Composite Endpoint from Randomization Through Study End - CEC Adjudicated – All Randomized Subjects with Extensive Metabolizer Functional Group (EM) ..... - 16 -
Table 8 Number and Percentage of Subjects Reaching the Composite Endpoint from Randomization Through Study End - CEC Adjudicated – All Randomized Subjects with Reduced Metabolizer Functional Group (RM) ..... - 18 -
Table 9 Heterogeneity Test ..... - 19 -
Table 10 Subgroup Analysis, Genetics Population ..... - 20 -

List of Figures

Figure 1 Hazard ratio comparing the primary efficacy endpoint (composite of CV death, nonfatal MI, or nonfatal stroke) for those patients in the All ACS population of the genetic subgroup receiving prasugrel: 2-bin functional grouping. ..... - 12 -
Figure 2 Hazard ratio comparing the primary efficacy endpoint (composite of CV death, nonfatal MI, or nonfatal stroke) for those patients in the UA/NSTEMI population of the genetic subgroup receiving prasugrel: 2-bin functional grouping. ..... - 13 -
Figure 3 Hazard ratio comparing the primary efficacy endpoint (composite of CV death, nonfatal MI, or nonfatal stroke) for those patients in the All ACS population of the genetic subgroup receiving clopidogrel: 2-bin functional grouping. ..... - 14 -
Figure 4 Hazard ratio comparing thy endpoint (composite of CV death, nonfatal MI, or nonfatal stroke) for those patients in the UA/NSTEMI population of the genetic subgroup receiving clopidogrel: 2-bin functional grouping. ..... - 15 -
Figure 5 Kaplan-Meier Estimates of the Incidence of the Composite Endpoint. All ACS (EM) ..... - 17 -

Figure 6 Kaplan-Meier Estimates of the Incidence of the Composite Endpoint. UA/NTEMI (EM) ..... - 17 -
Figure 7 Kaplan-Meier Estimates of the Incidence of the Composite Endpoint. All ACS (RM) ..... - 18 -
Figure 8 Kaplan-Meier Estimates of the Incidence of the Composite Endpoint. UA/NTEMI (RM) ..... - 19 -

1. EXECUTIVE SUMMARY

1.1 Conclusions and Recommendations

Based on my evaluation, the genetic sample is not a proper representative of the ITT population. Thus, whatever the genetics sample seems to suggest may not be applicable to the entire population under the study. Given that the genetics sample shows little treatment difference on the primary composite event, the apparent inconsistency between the intent-to-treat patients and the genetic consented patients, and the heterogeneity between the EM and RM subgroups in the genetic sample are extremely difficult to interpret. The results of these exploratory analyses do not provide useful information for the drug labeling.

1.2 Brief Overview of Genomic Studies

This sNDA includes one study (TAAL) to support the safety and efficacy of prasugrel in patients with acute coronary syndromes (ACS) who were to undergo PCI. The DNA samples were collected in the subset of patients from study TAAL who signed separate informed consents. The genetic data from these patients was analyzed. The primary endpoint of the trial was a comparison of the time to first occurrence of any event of the composite of cardiovascular (CV) death, nonfatal myocardial infarction (MI), or nonfatal stroke between patients randomized to prasugrel and patients randomized to clopidogrel.

Pending review of clinical efficacy study, this is the statistical review of genetics study.

1.3 Statistical Issues and Findings

The genetic study is a convenient sample of the ITT population, it is not a good representative of the entire patient cohort under study. While the entire population clearly showed a statistically significant benefit with prasugrel, the genetic subset showed little difference in the incidence rate of the clinical events between the two drug groups. All genetic analyses are considered exploratory.

2. Introduction

2.1 Overview

Prasugrel HCl (LY640315, CS-747; hereafter referred to as prasugrel) is a member of the thienopyridine class of platelet inhibitor drugs. Including clopidogrel, prasugrel is a pro-drug that must be activated in vivo through a process that is dependent on cytochrome P450 (CYP) metabolizing enzymes. The active metabolites bind to and inhibit the function of platelet P2Y12 receptors, with the magnitude of inhibition apparently related to clinical efficacy.

2.2 Statistical Methodology

In the genetics sub study, the primary hypothesis was tested using a Cox proportional hazards model with the following terms: treatment, binned functional group (EMfg/RMfg), and treatment-by-binned-functional group interaction. A Cox proportional hazards model was then used to test the efficacy between the EMfg and RMfg groups, and between the EMfg and IM2C19 and PMfg groups for each drug.

2.3 Data Sources

The sponsor's SAS datasets (SUBJINFO.XPT, CECF.XPT, CVTREAT.XPT, HEADER.XPT, TAALDG.XPT, TAALGENE.XPT, TAALVLG.XPT) were stored at IPRG, FDA.

3. STATISTICAL EVALUATION

3.1 Evaluation of Efficacy

3.1.1 Patient Disposition, Demographic and Baseline Characteristics

Table 1 summarizes genetic sample patient disposition, demographic and baseline characteristics. The mean age of this subset is about 60 years old; 70% are males; majority is Caucasian; average body weight of 82 kg. Most of patients had creatinine clearance >60 unit. Mean TIMI risk score is 3.8 for all ACS population, and 2.5 for UA/USTEMI population. Most patients had abnormal ECG, elevated level of troponin and CKMB at baseline and elevated cardiac marker. Less than a half of patients had metabolic syndrome. Only small percentage of patients had history of CHF, prior CABG, prior TIA/stroke, prior MI, and prior PCI. About 20% patients had diabetes. The demographic and baseline characteristics for the ITT population are also summarized, see Table 2.

Table 1 Patient Disposition, Demographic and Baseline Characteristics, Genetics Population

	UA/NSTEMI		STEMI		ALL ACS	
	Prasugrel	**Clopidogrel**	**Prasugrel**	**Clopidogrel**	**Prasugrel**	**Clopidogrel**
N	**880**	**914**	**374**	**366**	**1254**	**1280**
Age (yr)						
Mean	61.2	60.5	58.0	58.5	60.3	59.9
SD	10.64	11.00	10.46	11.25	10.68	11.10
<65 N	536	577	267	248	803	825
%	60.91	63.13	71.39	67.76	64.04	64.25
≥65 N	344	337	107	118	451	455
%	39.09	36.87	28.61	32.24	35.96	35.55
<70 N	661	710	313	297	974	1007
%	75.11	77.68	83.69	81.15	77.67	78.67
≥70 N	219	204	61	69	280	273
%	24.89	22.32	16.31	18.85	22.33	21.33
<75 N	766	810	350	333	1116	1143

	%	87.05	88.62	93.58	90.98	89.00	89.30
≥75	N	114	104	24	33	138	137
	%	12.95	11.38	6.42	9.02	11.00	10.70
Sex							
Female	N	249	290	94	93	343	383
	%	28.30	31.73	25.13	25.41	27.35	29.92
Male	N	631	624	280	273	911	897
	%	71.70	68.27	74.87	74.59	72.65	70.08
Ethnicity							
Caucasian	N	852	885	372	365	1224	1250
	%	96.82	96.83	99.47	99.73	97.61	97.66
African	N	3	5	1	1	4	6
	%	0.34	0.55	0.27	0.27	0.32	0.47
Hispanic	N	17	17	0	0	17	17
	%	1.93	1.86	0	0	1.36	1.33
Asian	N	3	5	1	0	4	5
	%	0.34	0.55	0.27	0	0.32	0.39
Other	N	5	2	0	0	5	2
	%	0.57	0.22	0	0	0.40	0.16
Weight (kg)							
<50	N	9	6	8	5	17	11
	%	1.02	0.66	2.14	1.37	1.36	0.86
≥50<70	N	162	159	60	79	222	238
	%	18.41	17.40	16.14	21.58	17.7	18.59
≥70<90	N	447	477	201	162	648	639
	%	50.80	52.19	53.74	44.26	51.67	49.92
≥90	N	262	272	105	120	367	392
	%	29.77	29.76	28.07	32.79	29.27	30.63
Creatinine Clearance							
<30	N	4	3	2	0	6	3
	%	0.46	0.33	0.54	0	0.48	0.24
30-60	N	72	92	30	45	102	137
	%	8.28	10.09	8.09	12.36	8.22	10.74
>60	N	794	817	339	319	1133	1136
	%	91.26	89.58	91.37	87.64	91.30	89.03
TIMI Risk Score							
0-2	N	92	105	182	161		
	%	10.53	11.60	61.49	56.29		
3-4	N	569	589	81	79		
	%	65.10	65.08	27.36	27.62		
5-7	N	213	211	-	-		
	%	24.37	23.30				
5-14	N	-	-	33	46		
	%			11.15	16.08		
Mean		3.81	3.75	2.33	2.54		
SD		1.13	1.14	1.71	1.82		
Minimum		0	0	0	0		
Maximum		7	7	9	9		
TIMI Risk Index							
Q1: 3.90-13.60	N	177	203	87	100	264	303
	%	20.11	22.23	23.32	27.32	21.07	23.69
Q2: >13.60-17.50	N	181	191	80	76	261	267

%	20.57	20.92	21.45	20.77	20.83	20.88
Q3: >17.50-21.70 N	186	200	79	62	265	262
%	21.14	21.91	21.18	16.94	21.15	20.48
Q4: >21.70-27.40 N	171	165	60	62	231	227
%	19.43	18.07	16.09	16.94	18.44	17.75
Q5: >27.40-94.00 N	165	154	67	66	232	220
%	18.75	16.87	17.96	18.03	18.52	17.20
Mean	20.67	20.24	19.87	20.22	20.43	20.23
SD	8.50	8.50	8.21	9.53	8.42	8.80
Minimum	4.8	4.8	5.9	4.8	4.8	4.8
Maximum	86.30	69.5	50.8	65.70	86.30	69.5
History of CHF						
Yes N	32	22	5	5	37	27
%	3.64	2.41	1.34	1.37	2.95	2.11
No N	848	892	369	361	1217	1253
%	96.36	97.59	98.66	98.63	97.05	97.89
Metabolic Syndrome						
Yes N	392	433	146	152	538	585
%	44.55	47.37	39.04	41.53	42.9	45.7
No N	488	481	228	214	716	695
%	55.45	52.63	60.96	58.47	57.10	54.3
ECG Abnormality						
Yes N	697	693	373	363	1070	1056
%	79.20	75.82	99.73	99.18	85.33	82.50
No N	183	221	1	3	184	224
%	20.80	24.18	0.27	0.82	14.67	17.50
Troponin over ULN at Baseline						
Yes N	575	611	171	176	746	787
%	74.29	76.95	59.17	61.97	70.18	73.01
No N	199	183	118	108	317	291
%	25.71	23.05	40.83	38.03	29.82	26.99
CKMB over ULN at Baseline						
Yes N	495	530	231	245	726	775
%	56.70	58.82	63.11	70.20	58.6	62.00
No N	378	371	135	104	513	475
%	43.30	41.18	36.89	29.80	41.40	38.00
Any Elevated Cardiac Marker						
Yes N	673	708	263	271	936	979
%	76.48	77.46	70.32	74.04	74.64	76.48
No N	207	206	111	95	318	301
%	23.52	22.54	29.68	25.96	25.36	23.52
Prior CABG						
Yes N	63	48	3	3	66	51
%	7.16	5.25	0.80	0.82	5.26	3.98
No N	817	866	371	363	1188	1229
%	92.84	94.75	99.20	99.18	94.74	96.02
Prior TIA/						

stroke						
Yes N	35	36	6	9	41	45
%	3.98	3.94	1.6	2.46	3.27	3.52
No N	845	878	368	357	1213	1235
%	96.02	96.06	98.4	97.54	96.73	96.48
Diabetes						
Yes N	205	225	61	59	266	284
%	23.3	24.62	16.31	16.12	21.21	22.19
No N	675	689	313	307	988	996
%	76.7	75.38	83.69	83.88	78.79	77.81
Prior MI						
Yes N	183	171	35	28	218	199
%	20.8	18.71	9.36	7.65	17.38	15.55
No N	687	743	339	338	1036	1081
%	79.2	81.29	90.64	92.35	82.62	84.45
Prior PCI						
Yes N	113	113	16	20	129	133
%	12.84	12.36	4.28	5.46	10.29	10.39
No N	767	801	358	246	1125	1147
%	87.16	87.64	95.72	94.54	89.71	89.61

(Source: Reviewer's analysis)

Table 2 Demographic and Baseline Characteristics, ITT population

	UA/NSTEMI		STEMI		ALL ACS	
	Prasugrel	Clopidogrel	Prasugrel	Clopidogrel	Prasugrel	Clopidogrel
N	5044	5030	1769	1765	6813	6795
Age (yr)						
Mean	61.5	61.3	59	59.8	60.9	61.0
SD	11.19	11.35	11.21	11.65	11.25	11.45
<65 n	2987	3000	1201	1134	4188	4134
%	59.22	59.64	67.89	64.25	61.47	60.84
≥65 n	2057	2030	568	631	2625	2661
%	40.78	40.36	32.11	35.75	38.53	39.16
<70 n	3728	3730	1417	1366	5145	5096
%	73.91	74.16	80.10	77.39	75.52	75.00
≥70 n	1316	1300	352	399	1668	1699
%	26.09	25.84	19.00	22.61	24.48	25.00
<75 n	4328	4344	1584	1543	5912	5887
%	85.80	86.36	89.54	87.42	86.78	86.64
≥75 n	716	686	185	222	901	908
%	14.20	13.64	10.46	12.58	13.22	13.36
Sex						
Female n	1325	1399	380	419	1705	1818
%	26.27	27.81	21.48	23.74	25.03	26.75
Male n	3719	3631	1389	1346	5108	4977
%	73.73	72.19	78.52	76.26	74.97	73.25
Ethnicity						
Caucasian n	4575	4569	1688	1705	6263	6274
%	90.70	90.83	95.42	96.60	91.93	92.33
African n	177	168	28	19	205	187
%	3.51	3.34	1.58	1.08	3.01	2.75