

**Table 2: Efficacy Outcomes**

Event	Dabigatran 110 mg N=6015		Dabigatran 150 mg N=6076		Warfarin N=6022		Dabigatran 110 mg vs. Warfarin			Dabigatran 150 mg vs. Warfarin			Dabigatran 150 mg vs. 110 mg		
	N	Rate/ 100 Person Yrs	N	Rate/ 100 Person Yrs	N	Rate/ 100 Person Yrs	RR	95% CI	P Values	RR	95% CI	P Values	RR	95% CI	P
Stroke or systemic embolism	183	1.54	134	1.11	202	1.71	0.90	0.74- 1.10	<0.001 (NI)  0.29 (sup)	0.65	0.52- 0.81	<0.001 (NI)  <0.001 (sup)	0.72	0.58- 0.90	0.004
Stroke	171	1.44	122	1.01	186	1.58	0.91	0.74- 1.12	0.38	0.64	0.51- 0.81	<0.001	0.70	0.56- 0.89	0.003
Hemorrhagic	14	0.12	12	0.10	45	0.38	0.31	0.17- 0.56	<0.001	0.26	0.14- 0.49	<0.001	0.85	0.39- 1.83	0.67
Ischemic or Unspecified	159	1.34	111	0.92	143	1.21	1.11	0.88- 1.39	0.35	0.76	0.59- 0.97	0.03	0.69	0.54- 0.88	0.002
Non-disabling Stroke	60	0.50	44	0.37	69	0.58	0.86	0.61- 1.22	0.40	0.62	0.43- 0.91	0.01	0.72	0.49- 1.07	0.10

Disabling or Fatal Stroke	112	0.94	80	0.66	119	1.01	0.93	0.72- 1.21	0.61	0.66	0.50- 0.87	0.004	0.70	0.53- 0.94	0.02
Myocardial Infarction	98	0.82	97	0.81	75	0.64	1.29	0.96- 1.75	0.09	1.27	0.94- 1.71	0.12	0.98	0.74- 1.30	0.88
Silent Myocardial Infarction	11	0.09	8	0.07	9	0.08	1.22	0.50- 2.93	0.66	0.87	0.34- 2.27	0.78	0.72	0.29- 1.79	0.48
Pulmonary embolism	14	0.12	18	0.15	12	0.10	1.16	0.54 - 2.51	0.71	1.47	0.71- 3.06	0.30	1.27	0.63- 2.56	0.50
Hospitalization	2312	19.4	2430	20.2	2458	20.8	0.92	0.87- 0.97	0.003	0.97	0.92- 1.03	0.34	1.06	1.00- 1.12	0.04
Death from vascular causes	289	2.43	274	2.28	317	2.69	0.90	0.77- 1.06	0.21	0.85	0.72- 0.99	0.04	0.94	0.79- 1.11	0.44
Death for any cause	446	3.75	438	3.64	487	4.13	0.91	0.80- 1.03	0.13	0.88	0.77- 1.00	0.051	0.97	0.85- 1.11	0.66

**NI=non-inferiority, sup=superiority**

**Table 3: Bleeding and Net Benefit**

Event	Dabigatran 110 mg		Dabigatran 150 mg		Warfarin		Dabigatran 110 mg vs. Warfarin			Dabigatran 150 mg vs. Warfarin			Dabigatran 150 mg vs. 110 mg		
	N	Rate/100 Person Yrs	N	Rate/100 Person Yrs	N	Rate/100 Person Yrs	RR	95% CI	p	RR	95% CI	P	RR	95% CI	P
Any Major Bleeding	342	2.87	399	3.32	421	3.57	0.80	0.70- 0.93	0.003	0.93	0.81- 1.07	0.31	1.16	1.00- 1.34	0.04
- Life threatening	147	1.24	179	1.49	218	1.85	0.67	0.54- 0.82	<0.001	0.80	0.66- 0.98	0.03	1.21	0.97- 1.50	0.09
- Non life threatening	218	1.83	248	2.06	226	1.92	0.96	0.80- 1.15	0.65	1.08	0.90- 1.30	0.39	1.13	0.94- 1.36	0.19
- Gastro-intestinal	137	1.15	188	1.56	126	1.07	1.08	0.85- 1.38	0.52	1.48	1.18- 1.85	0.001	1.36	1.09- 1.70	0.006
Minor Bleeding	1566	13.16	1787	14.85	1931	16.37	0.79	0.74- 0.84	<0.001	0.91	0.86- 0.97	0.005	1.16	1.09- 1.24	<0.001
Major or Minor Bleeding	1754	14.74	1993	16.56	2166	18.37	0.78	0.73- 0.83	<0.001	0.91	0.85- 0.96	0.002	1.16	1.09- 1.23	<0.001
Intra-cranial Bleeding	27	0.23	38	0.32	90	0.76	0.30	0.19- 0.45	<0.001	0.41	0.28- 0.60	<0.001	1.39	0.85- 2.28	0.19
Extra-cranial Bleeding	317	2.66	364	3.02	335	2.84	0.94	0.81- 1.10	0.42	1.07	0.92- 1.24	0.36	1.14	0.98- 1.33	0.09

Net clinical benefit outcome	873	7.34	855	7.11	933	7.91	0.92	0.84- 1.01	0.09	0.90	0.82- 0.99	0.02	0.97	0.88- 1.07	0.56
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p values are for superiority. Hemorrhagic stroke was counted both as a stroke in Table 2, as a major/life-threatening bleeding and is part of intra-cranial bleeding in Table 3.