Appendix 2 (as supplied by the authors): Characteristics of the NI trials of oral anticoagulants

Trial/Author	Name of drug	Duration of therapy and fol.up (days)	Dosage of enoxaparin	Primary endpoint	NI margin	Method to determine NI margin	Start of recruitment	Mean age of subjects	Female subjects (%)	Number of subjects
Colwell, et.al.(1)	Ximelagatran	7-12	30 mg bid	Total VTE (symptomatic or venographic DVT or PE)	RD = 5%	- Independent clinical expert committee - Same NI margin as published NI trial on Tinzarapin vs Enoxaparin	Mar 2000	65	52	1838
EXPRESS. (2)	Dabigatran	8-12	40 mg qd	Major VTE (proximal DVT measured with venography, pulmonary embolism and/or death where PE could not be ruled out)	RD = 2%	Not described	Apr 2001	67	50	2835
REMODEL (3)	Dabigatran	6-10	40 mg qd	Composite of total VTE (symptomatic or venographic DVT or symptomatic PE) and all-cause mortality	RD = 9.2%	- 67% preserved-effect of difference between enoxaparin and placebo - Based on one published placebo controlled trial	Nov 2004	68	65	2183
RE MOBILIZE (4)	Dabigatran	12-15	30 mg bid	Composite of total VTE (symptomatic or venographic DVT or	RD = 9.2%	- 67% preserved-effect of	Nov 2004	66	58	2615

Appendix to: Wangge G, Roes KCB, de Boer A, et al. The challenges of determining noninferiority margins: a case study of noninferiority randomized controlled trials of novel oral anticoagulants. *CMAJ* 2012; DOI:10.1503/cmaj.120142.

				symptomatic PE) and all-cause mortality		difference between enoxaparin and placebo - Based on one published placebo controlled trial				
Re-Novate (5)	Dabigatran	28-35	40 mg qd	Composite of total VTE (symptomatic or venographic DVT or symptomatic PE) and all-cause mortality	RD = 7.7%	- 67% preserved-effect of difference between enoxaparin and placebo - Based on pooled analysis of 3 placebo controlled trials	Dec 2004	64	56	3613
EXTEND (6)	Ximelagatran	32-38	40 mg qd	Major VTE (proximal DVT as diagnosed at end-of-treatment, any clinically suspected and objectively confirmed DVT, measured by bilateral compression ultrasound clinically suspected and objectively confirmed PE and VTE-related death or death where VTE-related causes could not be excluded)	RD = 2%	Not described	Sep 2005	65	54	1158
RECORD 1(7)	Rivaroxaban	35	40 mg qd	Composite of DVT measured with venography, nonfatal PE	RD = 3.5%	Not described	Feb 2006	63	56	4541

Appendix to: Wangge G, Roes KCB, de Boer A, et al. The challenges of determining noninferiority margins: a case study of noninferiority randomized controlled trials of novel oral anticoagulants. *CMAJ* 2012; DOI:10.1503/cmaj.120142.

				and all-cause mortality						
RECORD 3(8)	Rivaroxaban	10 - 14	40 mg qd	Composite of DVT measured with venography, nonfatal PE and all-cause mortality	RD = 4%	Not described	Feb 2006	68	68	2531
RECORD 4 (9)	Rivaroxaban	11-15	30 mg bid	Composite of DVT measured with venography, nonfatal PE and all-cause mortality	RD = 4%	Not described	Jun 2006	65	65	3148
ADVANCE 1 (10)	Apixaban	10 - 14	30 mg bid	Composite of DVT measured with venography, nonfatal PE and all-cause mortality	RD = 5.6% RR = 1.25	Not described	Nov-20061	66	61	3195
ADVANCE 3(11)	Apixaban	32-38	40 mg qd	Composite of DVT measured with venography, nonfatal PE and all-cause mortality	RR = 1.25	Not described	Mar 2007	61	53	5407
ADVANCE 2 (12)	Apixaban	10 - 14	40 mg qd	Composite of DVT measured with venography, nonfatal PE and all-cause mortality	RD = 5.6% RR = 1.25	Not described	Jun 2007	67	72	3057

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Appendix to: Wangge G, Roes KCB, de Boer A, et al. The challenges of determining noninferiority margins: a case study of noninferiority randomized controlled trials of novel oral anticoagulants. *CMAJ* 2012; DOI:10.1503/cmaj.120142.

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