Corrected clarification questions

Amendments are shown in red text

A4. Priority Question: Please complete the following table for RE-COVER I, RE-COVER II, REMEDY, and RESONATE for the listed subgroups in the full randomised, full analysis and per protocol populations (that is, 30 tables [b and c not applicable for RESONATE]):

a. Western Europe region;

b. INR control as measured by percentage time in therapeutic range (TTR) for centres in the warfarin group with TTR <60%;

c. INR control as measured by percentage time in therapeutic range (TTR) for centres in the warfarin group with TTR ≥60%.

	Dabigatran			Warfarin			Dabigatran vs. Warfarin	
	n	N	Event rate (100 pt-year)	n	N	Event rate (100 pt-year)	Hazard Ratio (95% CI)	p-value
Composite of recurrent symptomatic VTE and deaths related to VTE								
Symptomatic PE								
Symptomatic DVT								
Deaths related to VTE								
All deaths								
Major bleed								
Clinically relevant bleed								
Composite of all major and clinically relevant bleeding events								
Any bleeding event								
ICH								
GI bleed								

A 12. Please complete the table below to provide a breakdown of the types and frequency of adverse event that led to treatment discontinuation in each of the RE-COVER I treatment groups for the ITT population. Please complete similar tables for RE-COVER

II, REMEDY and RESONATE. If this information is available in the CSRs, please also provide the page and table numbers.

	ITT Population					
	Dabigatran			Warfarin		
	n	N	Event rate (100 pt-year)	n	N	Event rate (100 pt-year)
Adverse event (please specify [add additional table rows below as necessary]):						
Adverse event:						

A18. **Priority Question** Please clarify which trials were used in the AIC for dabigatran versus warfarin via placebo described on page 145 that resulted in an RR 0.65 (95% CI: 0.15 to 2.87).

A22. Please provide the citations and references for:

a) the 35 studies included in the original systematic review (MS; pg 55);

b) the additional six studies identified in the systematic review update (MS; pg 56);

c) the 30 studies included in the meta-analysis (MS; Figure 18, pg 154);

d) the 5 studies excluded from the meta-analysis (MS; Figure 18, pg 154) along with the reasons for their exclusion.