IV. Overall Conclusions

RMP version 1.0 with data lock point and final sign off date of 07-05-2026 is acceptable. The following summary table of safety concerns is agreed:

Summary of safety concerns	
Important identified risks	• Haemorrhage
Important potential risks	• Embryo-fetal toxicity
Missing information	• Remedial pro-coagulant therapy for excessive haemorrhage • Patients with atrial fibrillation (AF) and prosthetic heart valve

Additional risk minimisation measures in the form of educational materials are in place for the following safety concern:

- Haemorrhage

The educational material consists of the following elements:

- Prescriber guide
- Patient alert card

Summary
The previously agreed conditions to the Marketing Authorisation remain valid and are still outstanding. The following conditions are in place:

- aRMMs in the form of educational materials are in place for the following safety concern:
    - Haemorrhage

- The educational material consists of the following elements:
    - Prescriber guide
    - Patient alert card