


ERA saved our client time and money in complex Workshare Procedure

Challenge:	Solution:	How we excelled:
 <ul style="list-style-type: none">➤ Client proposed multiple changes to Module 3 of the dossier of Biological Medicinal Product via Worksharing Variation across multiple MAs (including Nat, MRP & DCP procedures)➤ ERA was provided with the list of changes which included the variation category for each change (to facilitate a speedy submission)	<ul style="list-style-type: none">➤ ERA reviewed all the proposed changes against the relevant currently approved dossier sections of Module 3 to confirm the categories proposed by the Client were correct (to avoid validation issues)➤ ERA amended the variation categories proposed by the Client to align better with the variation guideline for the required changes➤ All changes were explained and connected to each other by ERA to demonstrate how they were consequential, in a document attached to the Cover Letter➤ ERA was able to reduce the number of variations required by identifying which changes were 'consequential'. This reduced the time required to prepare the application, thereby reducing the regulatory burden and the cost for the client➤ ERA also supported the client by; approaching the RMS to apply for a workshare variation, submitting the application to all MS, helped the Client respond to some queries received during assessment and was also involved in the Nat phase process after the approval of this workshare variation➤ ERA helped the client to increase efficiency of the NCA assessment which resulted in approval being received in a timely manner	<ul style="list-style-type: none">➤ ERA team are adaptable and were able to manage this complex worksharing variation by working together, as each member of the team has over 18 years' experience each in the pharmaceutical industry➤ This level of knowledge and extensive expertise facilitated the efficient application of CMDh Guidance documents when preparing this application➤ ERA have a wealth of knowledge & experience as a result of working with the various EU NCAs and could provide the client with a full regulatory solution which resulted in the successful outcome for this procedure

Outcome: Approval of complex workshare variation in a timely manner