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web within the european union eu there is a requirement to
submit a risk management plan rmp for a proposed new drug
at the time of submission of the marketing authorisation
application maa an rmp may also be needed for existing
products when there is a significant change to the maa
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03 2023
web publication of risk management plan rmp summaries
analysis of the experience of the 1 year pilot phase presented
by juan garcia burgos and caroline voltz outline background
on rmp summaries and pilot phase objectives of the analysis
results conclusions and way forward why produce a summary
of the risk management plan