

CONTENTS

Summary	1
Summary (In Japanese)	2
Introduction	5
Objective	11
Methodology	13
Response Rate	15
Results	17
Section 1A – Company strategy	17
Development of the dossier	19
Strategies for timing	22
Changes in policy	25
Repetition of clinical studies	26
Application of clinical data	28
Section 1B – Company experience	35
Section 2 – Compound related information	43
Discussion	55
Conclusion	61
References	63
Appendices	65
The questionnaire	67
Companies invited to participate	77
Dates of completion of clinical studies and of submission in each region	79