

# CONTENTS

---

<b>KEY MESSAGES .....</b>	<b>3</b>
<b>INTRODUCTION .....</b>	<b>7</b>
<b>OBJECTIVES .....</b>	<b>9</b>
<b>METHODOLOGY .....</b>	<b>11</b>
<b>DEFINITIONS .....</b>	<b>13</b>
<b>RESULTS .....</b>	<b>15</b>
Response .....	15
Characterisation of the data set .....	15
Numbers of subjects and trials in dossiers .....	17
Trends in numbers of subjects and trials by year of dossier submission.....	18
Numbers of subjects and trials by phase: Is there a change over time? .....	19
Objectives of the clinical trials contained in the dossiers .....	21
Types of clinical trial and the dossier .....	22
Trials in special patient groups and for pharmacoeconomic purposes .....	23
Indications and the dossier .....	24
Location and date of dossier submission.....	25
The size of the dossier and re-engineering strategies .....	26
Commercial pressures and the size of the dossier .....	26
Re-engineering strategies .....	26
Reducing the number of trials conducted and subjects studied.....	27
Regulatory authorities and clinical development .....	28
Electronic submissions.....	29
<b>DISCUSSION.....</b>	<b>31</b>
<b>THE WAY FORWARD .....</b>	<b>41</b>
<b>ACKNOWLEDGEMENT.....</b>	<b>43</b>
<b>REFERENCES .....</b>	<b>45</b>
<b>APPENDIX 1, The questionnaire .....</b>	<b>47</b>

**APPENDIX 2, Companies invited to participate in this study ..... 49**