

# The 21<sup>st</sup> Century Take on Observational Studies

Using Real-World Evidence in the New Millennium

## Table of Contents

### Introduction

<b>21<sup>st</sup> Century Research: A New Approach .....</b>	<b>3</b>
<b>The Need for Evidence .....</b>	<b>5</b>
<b>Observational Studies: Research in the Real World .....</b>	<b>7</b>
<b>Survey – How Industry is Using Observational Studies .....</b>	<b>10</b>
<b>Challenges of Observational Studies .....</b>	<b>15</b>
<b>Trends in Observational Research .....</b>	<b>17</b>
<b>Conclusion: Great Expectations .....</b>	<b>19</b>
<b>Appendix .....</b>	<b>20</b>
A. FDA Guidance for Industry: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices	