

## Target Product Profile: Therapeutics Part 2 (Download [Part 1](#))

A Target Product Profile provides a structure for the scientific, technical, clinical, and market information that is required to achieve a desired commercial outcome. It provides all stakeholders with a clear vision of the product objectives and helps guide research and development decisions. It is a dynamic strategic document that should be reviewed throughout the development process.

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	<i>Description</i>	<i>Example</i>	
<b>Other Efficacy Measures</b>	Additional efficacy measures that may be recorded, but are not required to obtain a successful positive clinical trial result.	<ul style="list-style-type: none"> <li>• Reduction in nocturnal awakenings</li> <li>• Increased activity levels</li> <li>• Reduced sensitivity to environmental stimuli</li> <li>• Reduced number of work and school days missed</li> </ul>	
<b>Expected Safety Outcomes</b>	The most important safety outcome measures. Ideally should be easy to interpret and sensitive to treatment differences.	<i>Optimistic:</i> <ul style="list-style-type: none"> <li>• Rare hypersensitivity reactions</li> <li>• No increase in severe infections</li> <li>• Injection site reactions better than other biologics</li> </ul>	<i>Target:</i> <ul style="list-style-type: none"> <li>• Acceptable hypersensitivity reactions</li> <li>• No increase in severe infections</li> <li>• Injection site reactions similar to other biologics</li> </ul>
<b>Dosage and Administration</b>	Route and site of administration, dosage volume and frequency, administrating location and personnel.	<i>Optimistic:</i> <ul style="list-style-type: none"> <li>• 1 SC injection Q4 weeks</li> <li>• Flat dosing</li> <li>• Home use</li> </ul>	<i>Target:</i> <ul style="list-style-type: none"> <li>• 1 SC injections Q4 weeks</li> <li>• Flat dosing</li> <li>• Home use</li> </ul>
<b>Contraindications</b>	Known or expected contraindications	TBD	
<b>How Supplied</b>	Expected form and packaging information	Liquid injectable at product launch, addition of an auto-injector in the future.	