

Brief Instructions for the Form of Summary of the Orphan Drug/Medical Device

Form of summary of the orphan drug/medical device

Name of the orphan drug/medical device:

- Fill out as indicated in the application form of orphan designation.

Name of the company:

- Fill out as indicated in the application form of orphan designation.

Efficacy of the drug/medical device for the target disease, etc.:

- Fill out medical needs, results of clinical studies to date (including clinical studies conducted outside Japan) and development status, etc.

希少疾病用医薬品等概要
Summary of the Orphan Drug/Medical Device

名称 <i>Name of the orphan drug/medical device</i>	
予定される 効能・効果 <i>Expected indication</i>	
申請者名 <i>Name of the company</i>	
対象疾患について <i>Description of the target disease</i>	対象疾患の概略説明、患者数等を記載
対象疾患に対する本剤の効能・効果等について <i>Efficacy of the drug/medical device for the target disease, etc.</i>	医療上の必要性、これまでの臨床試験成績（外国を含む）、開発状況等を記載

(注) 1. 様式は A4 判とすること。
2. 詳細についてさらに説明を要する場合には、別添として添付することは差し支えない。

Fill out this form in Japanese.

Expected indication:

- Fill out as indicated in the application form of orphan designation.

Description of the target disease:

- Fill out a brief explanation of the target disease and the number of patients etc.

<Note>

1. Size of this form shall be A4.
2. Applicant may as well attach an accompanying sheet(s) for more detailed explanations, if needed.