

## Orphan Drug Development Guidebook

### Building Block J312

This document defines the content of the Building Block created for each identified tool, incentives, initiative or practice introduced by public bodies or used by developers to expedite drug development in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	AMED funded programs and resources
References	<a href="https://www.amed.go.jp/en/index.html">https://www.amed.go.jp/en/index.html</a>
Description	Japan Agency for Medical Research and Development (AMED) was founded in 2015 to provide seamless funding from basic research to practical application and adequate implementation of clinical studies/trials, in order to promote drug development in Japan. Several programs are open and available for funding opportunities, that will help research at various stages of development.
Category	Development Resources Building Block
Geographical scope	Mostly Japan. Limited projects offer support in collaboration with Japanese researchers, globally, including programs with specific emphasis in Asia.
Availability	Various programs are available. Some specifically call for rare diseases or orphan drug development.
Scope of use	Obtaining funding for basic research to practical application including clinical trials and studies associated with R&D of a product.
Stakeholders	<ul style="list-style-type: none"> <li>• Researchers and pharmaceutical companies where applicable</li> <li>• Funding Agency (AMED)</li> </ul>
Enablers/ Requirements	Typical funding process will open in November through February. Most programs will require the researcher to be affiliated with a

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	Japanese research institute. Some funding are available to pharmaceutical companies, or in collaboration of academia and pharma.
Output	Funding
Best time to apply and time window	At any time during product development. Duration of funding depends on the program, but usually varies between 1 to 3 academic years. Call for funding may be available throughout the year, but a typical funding schedule will start from November to be eligible for funding starting from next April.
Expert tips	<p>There are multiple programs available, and finding the best match for your product will be important.</p> <p>PROs: One of the largest scale funding available from basic research to practical application. Some programs may be applied through joint application from a pharma company. Different types of application are available throughout the year, especially focused between November and February.</p> <p>CONS: Mostly limited to funding within Japan, however, few programs provide collaborative research across the border.</p>