

Orphan Drug Development Guidebook

Building Block E129

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	EURORDIS Open Academy
References	https://openacademy.eurordis.org/summerschool/
Description	<p>Since its launch in 2008, the EURORDIS Summer School on Medicines Research & Development has taken place every year in Barcelona. The Summer School is made up of one week of face-to-face training (held in June in Barcelona) after completing the training modules provided in the open academy. The training aims to provide participants with the knowledge and skills needed to become experts in medicines research and development. Over 20 EURORDIS Summer School trainers provide the training each year.</p> <p>The EURORDIS Summer School training covers topics including: clinical trials methodology, clinical research, ethics in medicines development, regulatory affairs, health technology assessment and marketing authorisation.</p> <p>In 2015, a new format was developed for the Summer School that combines training for both expert patients and researchers.</p> <p>The Summer School is one of the products of the EURORDIS Open Academy, which encompasses as well the Winter School on translational research for example (https://openacademy.eurordis.org/winterschool/)</p> <p>Online training: Unit 1 - Medical Research and Development Unit 2 - Ethics in Medicines Development</p>

	<p>Unit 3 - Statistics in medicines research and development</p> <p>Unit 4 - Benefit-risk assessment and pharmacovigilance</p> <p>Unit 5 - The European Medicines Agency (EMA)</p> <p>Unit 6 - Medical Regulatory Framework and Procedures</p> <p>Unit 7 - Market access & HTA</p>
Category	Development Resources Building Block
Geographical scope	European Union and beyond
Availability	Mainly for patients and patient advocates but also useful for academic researchers & clinicians from the Rare Diseases Community
Scope of use	Helping patients interested in becoming advocates and researchers working in translational science.
Stakeholders	Content is developed and managed by EURORDIS with the help of the Summer School faculty (including LUMC, EMA, Catalan RD Platform).
Enablers / Requirements	Non
Output	It provides patient representatives and researchers with the skillset needed to be good advocates at e.g. regulatory meetings.
Best time to apply and time window	Not applicable
Expert tips	<p>PROs:</p> <ul style="list-style-type: none"> – Adapted to the needs of the RD Community – more than 400 alumni – Online training modules, which are available online for free for anyone to use.

	<p>CONs:</p> <ul style="list-style-type: none">– Except the Spanish version, the content is only available in English
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