

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 / EURORDIS School on Medicines Research & Development
References	https://openacademy.eurordis.org/
Description	<p>Since its launch in 2008, the EURORDIS (Summer) School on Medicines Research & Development has taken place face-to-face every year in Barcelona or online during the COVID pandemic. The Summer School is made up of one week in-person training (usually held in June in Barcelona) following the completion of pre-training modules provided onto the Open academy website.</p> <p>The programme aims to provide participants with the knowledge and skills needed to contribute to activities related to medicines research and development. 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.</p> <p>Alongside the Schools, e-learning courses are open to anyone to take on the website.</p>

	<p>E-learning for Medicines Research & Development:</p> <p>Course 1 - Medical Research and Development Course 2 - Ethics in Medicines Development Course 3 - Statistics in medicines research and development Course 4 - Medical Regulatory Framework and Procedures Course 5 - The European Medicines Agency (EMA) Course 6 - Benefit-risk assessment and pharmacovigilance Course 7 - Market access & HTA</p> <p>And:</p> <p>Recommendations on the required capabilities for patient engagement Conflict of interest in patient engagement</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	The EURORDIS Open Academy empowers patient advocates with knowledge and skills to take part in patient engagement roles side-by-side with all stakeholders and to advocate for rare diseases on a European and national level.
Stakeholders	Content is developed and managed by EURORDIS with the help of the Open Academy faculty (https://openacademy.eurordis.org/faculty/).
Enablers / Requirements	<p>E-Learning courses are open to anyone to take on the website.</p> <p>Schools are accessible via a call for application and a selection process. (To be checked onto the Open Academy website / EURORDIS Communication Channels)</p>
Output	It provides patient representatives (and researchers/clinicians) with the skillset needed to contribute to activities related to medicines research and development. e.g. EMA Protocol Assistance.
Best time to apply	Anytime

and time window	
Expert tips	<p>PROs:</p> <ul style="list-style-type: none"> – Adapted to the needs of the RD Community – more than 600 alumni (https://openacademy.eurordis.org/alumni/) – E-learning 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