

## Drug Repurposing Guidebook

### Building Block E145

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

ITEM	DESCRIPTION
Building Block (BB) Title	LifeArc Repurposing Medicines Toolkit
References	<p><a href="#">LifeArc</a> and the Medical Research Council (<a href="#">MRC</a>):</p> <p><a href="#">New toolkit launched to help repurposed medicines reach patients.</a> 10 Oct 2022</p> <p><a href="#">Repurposing Medicines Toolkit - Guidance for navigating the process</a></p> <p><a href="#">Repurposing medicines: the opportunity and the challenges</a>, summary of a <a href="#">workshop</a> findings.</p>
Description	Tool is intended to stimulate thinking on the drug repurposing, including opportunities and challenges. It is not intended to be a step-by-step guide.
Category	Supporting tools
Type of BB	Development resource
Geographical scope	Europe
Availability	Charities, not-for-profit organization, including patients' organization, researchers/academic groups, and pharma companies.
Scope of use	<p>This BB provides high level considerations for the following key activities in the drug repurposing:</p> <ul style="list-style-type: none"> <li>• Target Product Profile (TPP)</li> <li>• Nonclinical discovery</li> </ul>

ITEM	DESCRIPTION
	<ul style="list-style-type: none"> <li>• Nonclinical development</li> <li>• Clinical development</li> <li>• Possible paths to patent access including “on-label” or “off-label” prescribing</li> <li>• Funding opportunities in UK</li> </ul>
Stakeholders involved	<ul style="list-style-type: none"> <li>• Researchers</li> <li>• Representatives of not-for-profit organization</li> <li>• Patients</li> <li>• Contract Research Organisation (CRO)</li> <li>• Medicines and Healthcare products Regulatory Agency (<a href="#">MHRA</a>)</li> <li>• National Institute for Health and Care Excellence (<a href="#">NICE</a>) and Scottish Medicines Consortium (<a href="#">SMC</a>).</li> <li>• NHS <a href="#">Medicines Repurposing programme</a> and <a href="#">Innovation service</a></li> </ul>
Enablers/ Requirements	Product is approved and marketed in UK for some “other” indication
Output	Tool provides a high-level outline of the key stages for the drug repurposing development. The tool is presented in a “Questions and Answers” format
Best time to apply and time window	No application is required. Best used at the time of the selection of the drug for repurposing, especially if UK is considered as a future market for the repurposed drug.
Expert tips	Best to be evaluated at early stage of drug development and re-evaluated during the drug development progression.