

Drug Repurposing Guidebook

Building Block I463

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	Pre-competitive space working
References	<p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4990051/</p> <p>https://futureoflife.org/data/documents/PreCompetitiveCollaborationInPharmaIndustry.pdf</p> <p>https://www.ncbi.nlm.nih.gov/books/NBK210038/</p> <p>https://www.nature.com/articles/nrd3602</p> <p>http://csmres.co.uk/cs.public.upd/article-downloads/Renal-precompetitive-consortium-(RPC2)-discovering-therapeutic-targets-together.pdf</p> <p>https://lawreview.law.ucdavis.edu/issues/48/4/Articles/48-4_Vertinsky.pdf</p>
Description	<p>Opportunity to combine complementary resources, expertise and skills across different organisations to help de-risk and/or support efficient evidence generation, and fast track development programmes.</p> <p>Key aim to bring multiple stakeholders together to address common joint issues (e.g., lack of natural history data, need for novel endpoint validation), and create a framework to develop an agreed solution that can benefit all.</p> <p>It enhances multi-stakeholder collaboration, which could produce faster and less resource intensive advances in a wide spectrum of activities versus working individually. Collaboration may come from a single organisation proposing to work together with another / others after identifying an issue, or from a group of organisations who have common goals and agree to conduct an activity jointly. Actual collaborative aspects may take different forms with varying degrees of formality.</p>

ITEM	DESCRIPTION
Category	Engagement with MA
Type of BB	Development practice
Geographical scope	International
Availability	Some jurisdictions have specific programmes with specific calls in particular areas from established frameworks (e.g. the European Innovative Medicines Initiative [IMI] - Public Private partnership), versus the opportunity to create a bespoke collaboration.
Scope of use	Need to clearly identify the boundaries and specific area that might benefit from precompetitive space working.
Stakeholders involved	Industry, academics, not-for-profit, patient groups, government institutions.
Enablers/ Requirements	<p>To agree the framework, rules of engagement and boundaries of the scope of the interactions in advance.</p> <p>Need to consider aspects such as ownership of intellectual property, data and extent of information sharing.</p>
Output	Improved productivity, helping to de-risk / share risk
Best time to apply and time window	Depends on the scope of the pre-competitive space activity.
Expert tips	Consider the costs involved in delivering a collaborative project, the need for available resourcing, create agreements and Terms of Reference in advance of starting the project, seek legal advice.