Drug Repurposing Guidebook

Building Block E141

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	Strengthening Training of Academia in Regulatory Science (STARS)
References	• STARS Common Strategy: Regulatory Support and Advice for Academia (https://www.csa-stars.eu/files/STARS_Common_Strategy.pdf) • Starokozhko et al., 2017, Strengthening Regulatory Science in academia: STARS, an EU initiative to bridge the translational gap, Drug Discov Today • Starokozhko et al., 2023, Strategic recommendations from the STARS project to foster academic drug development, NRDD. • Kallio et al., 2022 (Online Ahead of Print), Translating Academic Drug Discovery Into Clinical Development: A Survey of the Awareness of Regulatory Support and Requirements Among Stakeholders in Europe, Clin Pharmacol Ther • Website: https://www.csa-stars.eu/ • Slides are also available from the course "The Winding Road from a Brilliant Idea to Drug Approval: An Online Course in Regulatory Science for Academic Researchers". https://www.csa-stars.eu/Results-Pilot-I-Best-Practice-Transfer-1754.html.
Description	STARS was a collaboration of 21 partners from 18 countries, including the majority of the European national competent authorities (NCA), the European Medicines Agency, and the German Aerospace Center (DLR) Project Management Agency focusing on strengthening training of academia in regulatory science (STARS) in Europe. The project was supported by the European Commission's (EC) Framework Program for Research and Innovation Horizon 2020. It was running from 2019 until 2022

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Category	Regulatory and HTA engagement
Type of BB	Regulatory
Geographical scope	Europe
Availability	The STARS initiative was targeting academic and clinical researchers, however, the material can be accessible by any developer interested in this exercise.
Scope of use	The comprehensive inventory and presentations can be used to become more familiar with regulatory requirements. The course and the material prepared was not specifically focused on drug repurposing, but on clinical trials and bringing a medicine to the market in general. It provides clear recommendations how the dialogue between regulators and academic/clinical researchers and drug developers can be enhanced.
Stakeholders involved	Regulators, funders, academic/clinical researchers
Enablers/ Requirements	Being an academic/clinical researcher/SME aiming to develop a drug
Output	If you use this tool, then you access comprehensive training material prepared by regulatory bodies on how to develop a drug, and when it is best to interact with the Regulatory Authorities to check that the plan you're envisaging, fulfills the regulatory requirements/ expectations
Best time to apply and time window	Early in the development (as soon as you think your idea can become a drug)
Expert tips	- The project has just been deployed and so a running period is needed to collect tips. - Of note, from 2022 onwards it is intended to incorporate the recommendations from STARS in the European Regulatory Network, and changes are foreseen that increase among

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	others the dialogue between regulators and academic/clinical researchers.