Drug Repurposing Guidebook

Building Block E144

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	REMEDi4ALL
References	https://remedi4all.org/ https://twitter.com/REMEDi4ALL?s=20&t=rT7o_iqRGYpgLZA2UXWGjw www.eatris.eu
Description	**REMEDi4ALL** is a large-scale European Commission funded infrastructure project dedicated to advancing the field of medicines repurposing, comprising 24 partners from several sectors. Coordinated by EATRIS ERIC, the European infrastructure for translational medicine, REMEDi4ALL has two primary objectives: 1. *Assembling EU's "Bricks and Brains" to support high impact projects today and tomorrow* - To bring together a complete, multi-sectoral and accessible platform comprising the innovative approaches and cutting-edge technologies and expertise necessary to advise, support and advance a large volume of high potential drug repurposing projects at any stage of development. 2. *Future-proofing the repurposing process* – by bringing together all relevant stakeholders into a think-tank like environment to openly discuss, develop and debate the policy measures required to advance and sustain the eco-system for repurposing, so that 5-10 years from now disincentives to patient-centric drug repurposing are addressed and essentially eliminated. Key policy areas include – but are not limited to - economic models for fair pricing of repurposed drugs; regulatory mechanisms and incentives for repurposing; access to data, and funding policy.
Category	Supporting tools
Type of BB	Development resource

ITEM	DESCRIPTION
Geographical scope	Europe
Availability	REMEDi4ALL is available for users (researchers, charities, patient organizations, SME, funders, and pharma industry) that need research & development capacity, expertise, or advice for their drug repurposing project. A coordination team is available to explore collaboration and help find partner specific requests to support any step along the drug repurposing development value chain.
Scope of use	REMEDi4ALL can provide access to specific resources or expertise required to support drug repurposing development activities such as in silico tools (AI), predictive models (in vitro and in vivo), drug target validation, pharmaceutical development (e.g., reformulation), prediction of drug combinations (efficacy and safety). It specifically supports patient centric drug repurposing approaches (co-creation with patient champion). REMEDi4ALL can compile the right Drug Repurposing Development Team that can create a regulatory compliant Drug Repurposing Development Plan, tailored to the project needs and development stage.
Stakeholders involved	EATRIS ERIC is Coordinator of REMEDi4ALL. Preclinical researchers and clinical investigators involved in the consortium are testing and developing the platform during its construction phase. Additional users, ranging from academic researchers, pharma industry, SME/biotech can contact REMEDi4ALL for support in their project. Charities, funders and policy makers are encouraged to engage through the platform's stakeholder forum.
Enablers/ Requirements	The REMEDi4ALL platform can provide expertise, advice, provide support in developing the repurposing development plan (e.g., clear drug repurposing hypothesis/rationale, target product profile, gap analysis and critical path in research plan) and identify the service providers to execute the plan. Regulatory experts can be brought in upon an as need basis. Specific drug repurposing expertise will be gathered in expert teams in REMEDi4ALL that can perform a gap analysis of the project. Users can contact the platform for advice and explore collaborations. Once identified, the cost of the services has to be covered by the user. Public-private collaborations can be facilitated. A funders network is established during the construction phase.

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Output	Improved drug repurposing projects, regulatory compliant repurposing development plans, access to drug repurposing resources (preclinical and clinical), de-risked drug repurposing projects/portfolio, engagement with policy makers, education & training programs, international networking.
Best time to apply and time window	Continuously. REMEDi4ALL is in construction 2022-2023 after which it will be open to users to explore collaborative research projects and get access to specific drug repurposing expertise gathered in the platform. REMEDi4ALL can immediately be contacted to build a relationship and explore a collaboration with the platform.
Expert tips	Generate a Target Product Profile describing the repurposing drug minimal requirements and opportunities compared to current standard of care. This helps the generation of a clear development plan with the end goal in mind. Consider the medical need as a driver for the project and identify opportunities where patients can be involved in project design and/or decision making. Identify gaps in the project as detailed and as early as possible. Consult drug development, IP and regulatory experts to generate an understanding of the non-technical challenges of the development path. Consider that execution of the Repurposing Development Plan can require significant resources and can in some cases be as complex and costly as a conventional drug development project. In case pharmaceutical development activities are included (e.g., reformulation, dose adjustment or change to pediatric population), additional preclinical studies may be required that need to be considered in the funding strategy.