# Drug Repurposing Guidebook

Building Block I460

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 | Data outside the public domain |
| References | https://www.ema.europa.eu/en/about-us/how-we-work/access-documents<br><br>https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/output-european-medicines-agency-policy-access-documents-related-medicinal-products-human-veterinary_en.pdf<br><br>https://www.fda.gov/regulatory-information/freedom-information<br><br>https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7318194/ |
| Description | An advantage of drug repurposing is that the medicine under investigation has been studied in previous indication(s). Aside from information in the published literature and from documents provided by regulatory authorities such as assessment reports, EMA Clinical Data Publication, and clinical trials registries, there may be substantial data that is held elsewhere that is not readily available in the public domain but may be requested (including voluntary initiatives for data access by pharmaceutical companies). This BB provides a starting point to investigate and source that data. |
| Category | Availability of data |
| Type of BB | Development resource |

| ITEM | DESCRIPTION |
|---|---|
| Geographical scope | International |
| Availability | Different jurisdictions have different rules on the release of information held by public bodies. Some private bodies – notably pharmaceutical companies – may be willing to sharing information following formal requests and have processes to allow external groups to access information |
| Scope of use | Every repurposing project should run a gap analysis to determine what information might be held by different organisations that could be helpful for the future development programme |
| Stakeholders involved | Industry, academia, public bodies |
| Enablers/ Requirements | Helps reduce duplication and replication of experiments / and or clinical studies if relevant data has already been robustly generated elsewhere |
| Output | Adds to the portfolio of information around the medicine in the claimed indication, providing additional knowledge for shaping the development programme |
| Best time to apply and time window | Before embarking on any new work such as non-clinical experimentation or clinical trials consider if someone else might have already done it! |
| Expert tips | Consider all potential sources of information and draw up a strategy for requesting access to information held by different organisations, understand your rights in the different regions, contact individual companies with requests, check whether the provided information is suitable (e.g., quality and date the data was generated) before concluding on its relevance |