

Drug Repurposing: *What is it? What regulation is required? Is it commercially viable?*

Drug repurposing uses extensively tested drugs for additional or unrelated indications.^[1]

Used to expand therapy options or increase disease labels; frequently a use-case in Pediatrics

Example of a repurposed therapy

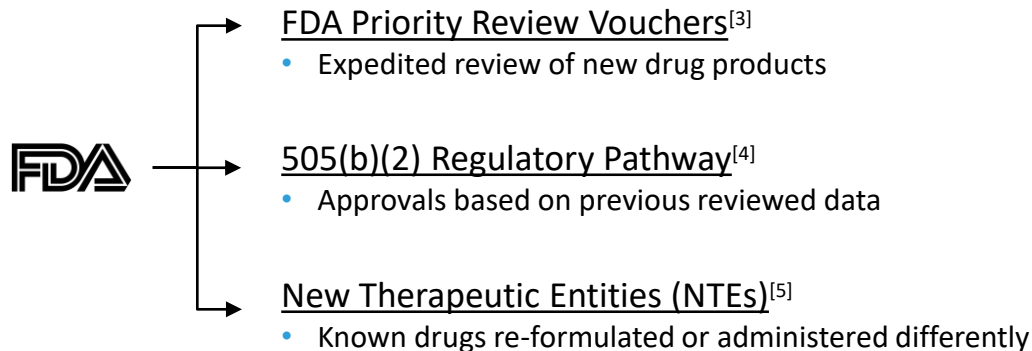


Rituximab

- First approved in 1997 for use B-cell malignances
- Received label expansion for refractory rheumatoid disease in 2006^[2] and first-line treatment for high-risk non-Hodgkin lymphoma in 2021^[2]

Considerations for drug repurposing include (1) regulatory pathway and (2) commercial factors:

1 Regulatory pathway



2 Commercial Factors



Strength of Intellectual Property (IP)
Composition of Matter > Method of Use > Process



Compelling value proposition

- Partner/Investor interest
- Commercial opportunity
- Strategic fit