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Barriers to successful drug repurposing, and approaches to overcoming them

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Abstract

Drug Repurposing not only has great potential for massively improved productivity in pharmaceutical R&D, but in some cases it has actually delivered. Notable examples include thalidomide and sildenafil, and more recently baricitinib for COVID-19. However, given that there are around 1,700 approved FDA drugs and over 7,800 indications[1], why are there not more examples? The key hurdle is not in the identification of repurposing hypotheses, but in their successful development, and in this respect, the barriers are commercial rather than scientific. The commercial incentives for repurposing are not so clear as for NCE R&D, despite the existence of multiple patent opportunities and even in some countries the availability of orphan marketing exclusivity for rare diseases. Successful drug repurposing requires the identification of a new product, differentiated from a generic for example by formulation, dose, route of administration. As an alternative to any of these approaches, repurposing may give rise to the development of a previously unmarketed product, such as a close analogue of a product, or a previously abandoned developmental compound. There are therefore multiple routes to successful repurposing development, but choices need to be made very soon after the discovery of a new indication, taking into account clinical, regulatory, CMC, patent and commercial factors. A range of examples will be provided to represent the possibilities.

Keywords

Commercial barriers, patenting, regulatory route

References

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