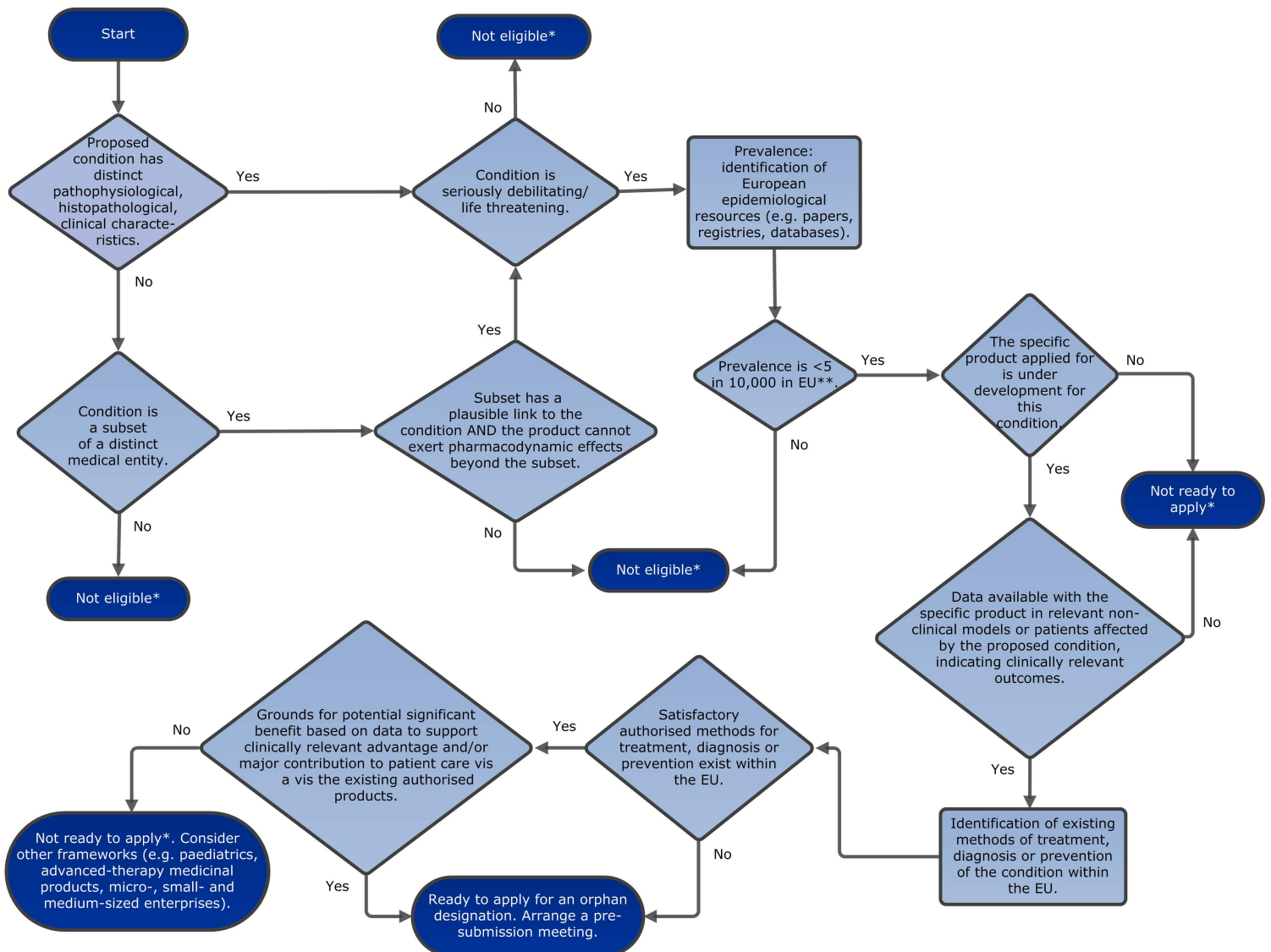


Sponsor's guide to an orphan designation



Disclaimer: The flowchart presented should be interpreted as a tool to guide potential sponsors through the orphan designation eligibility criteria. The flowchart is not used for the assessment of orphan designation, it is non-binding and it does not pre-empt any of the opinions obtained by the Committee for Orphan Medicinal Products.

*Contact the EMA orphan medicines office for more guidance.

**Article 3(1)(a) of Regulation (EC) No 141/2000 provides an alternative criterion to the prevalence number, based on evidence of insufficient return to justify the necessary investment.