



CLINICAL RELEVANCE

Safety & efficacy

Posology & method of administration

Cross-disease impact



DISEASE BURDEN

Prevalence & incidence

Treatment options

Disease severity

Epidemic risk



INTELLECTUAL PROPERTY LANDSCAPE

Years to patent expiry

Geographical coverage

Secondary patents

Multiple patent owners



SERVICE DELIVERY ENABLERS

Diagnostic

Companion drugs

Health system requirements





REGULATORY

Regulatory pathway

Regulatory cost & complexities

Probability of biowaiver/clinical trial waiver



MANUFACTURING

Manufacturing simplicity

Presentation & storage



MARKET

Affordability & availability of the candidate

Commercial potential for generic manufacturers

Impact