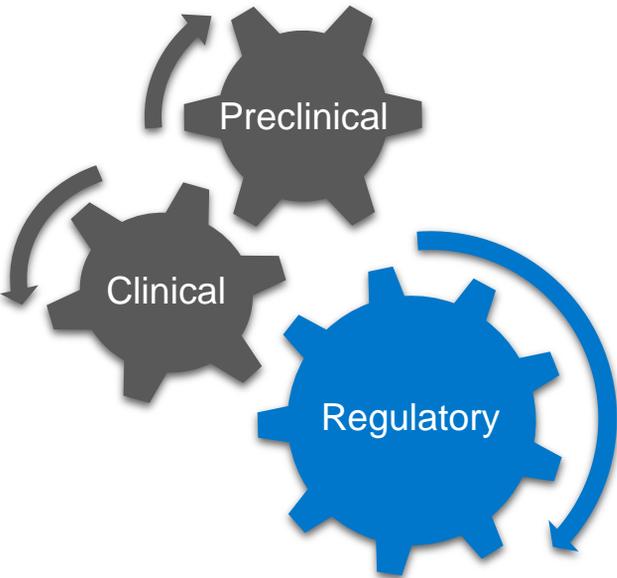


REGULATORY STRATEGY



Establish a Target Product Profile as a regulatory and product development planning tool



Align preclinical and clinical studies with regulatory requirements

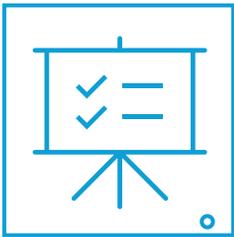


Engage with regulatory agencies throughout the program lifecycle for guidance

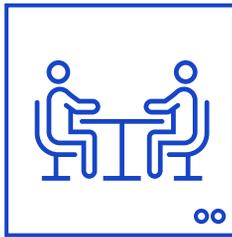


Utilize orphan product incentive programs and expedited pathways to accelerate development

Interactions and Documentation



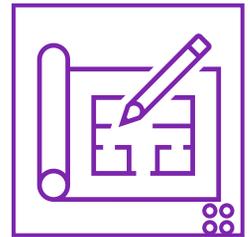
Consult available regulatory resources (e.g. guidance documents, other approved products)



Engage frequently with regulatory bodies through meetings for preliminary reviews and guidance



Prepare a comprehensive regulatory package with supporting data and literature



Develop a thorough clinical development plan, providing pertinent justification for each component



Early planning combined with regulatory alignment can effectively address the challenges of a drug development program

PaVe-GT relevant resources: [Target Product Profile](#), [INTERACT package](#), [FDA Incentives for orphan drug development](#), preIND and TypeC packages (coming soon)