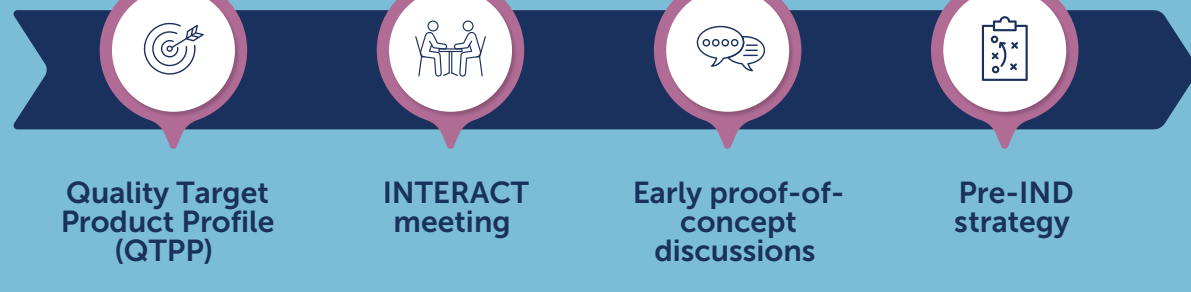


The 7 Regulatory Milestones Every Viral Vector Developer Should Plan For

A strategic roadmap from development to commercialisation based on a US > Global development strategy

STAGE 1

Target Product Profile & Early Agency Engagement



GOAL

Establish development direction and regulatory alignment



STAGE 2

Preclinical & IND-Enabling Development



GOAL

Build the package to support first-in-human studies



STAGE 3

IND & Early Clinical Development



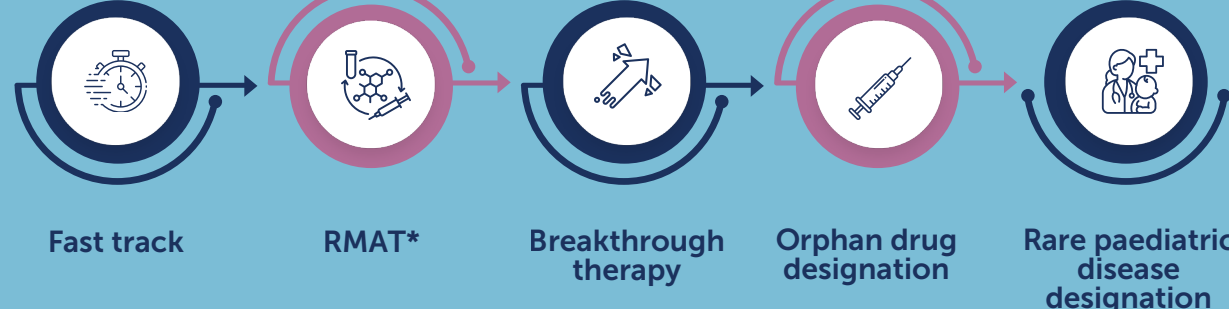
GOAL

Generate safety and early efficacy data



STAGE 4

Regulatory Designations & Agency Interactions



GOAL

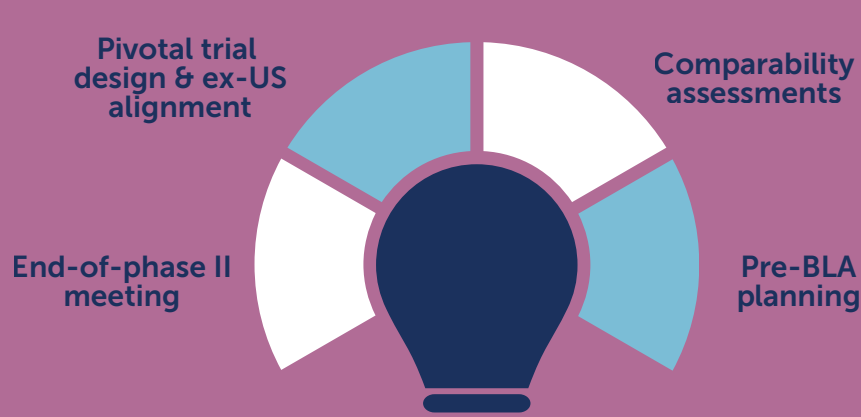
Increase engagement and accelerate development where appropriate

*RMAT: Regenerative Medicine Advanced Therapy



STAGE 5

Pivotal Development & Comparability



GOAL

Demonstrate readiness for registration



STAGE 6

BLA Review & Approval



GOAL

Achieve marketing authorisation

*PDUFA: Prescription Drug User Fee Act



STAGE 7

Commercialisation & Lifecycle Management



GOAL

Sustain product success beyond approval

The most successful programmes are not simply those with promising science. They are those supported by a regulatory strategy that aligns science, manufacturing, clinical development and commercial objectives from the outset.

At OXB, quality and regulatory excellence are central to everything we do. With decades of experience advancing viral vector therapies, we've helped bring products to patients worldwide by embedding quality and regulatory foresight into every stage of development and manufacturing.

Let's deliver life-changing therapies together

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To discuss your project, please contact our team at partnering@oxb.com