

PARTNERING WITH YOU AT EVERY STAGE





Starting the Project DEVELOPMENT/PROOF OF CONCEPT STAGE

- Platform Consultation
- Vector Design
- Plasmid Design
- Small Scale Productions

Advancing Toward Clinical Testing PRE-CLINICAL / IND-ENABLING

- Scaled Research Manufacturing
- Adherent or Suspension
 Production Routes
- Analytical Development
- IND and Regulatory Support

Entering Human Trials CLINICAL MANUFACTURING / PHASE I/II

- GMP Manufacturing with QA Oversight
- Adherent or Suspension Production Routes
- Enhanced Analytics
- DMF and Regulatory Support

Accelerating into the Marketplace PHASE III/COMMERCIAL

• Raw Material Testing

NEWCO

- Product Specific Process and Analytical Validation
- Fill/Finish/Packaging with Labeling and Serialization
- Manual & Automated Fill
- BLA and Regulatory Support

ANDELYN BIOSCIENCES IS YOUR FULL-SPECTRUM GENE THERAPY PARTNER. WORK WITH US FROM START TO FINISH OF YOUR PRODUCT OR PARTNER WITH US AT ANY STAGE OF YOUR PROJECT – PRECLINICAL THROUGH COMMERCIAL SCALE.