Renejix
DEVELOPMENT

NEW Prime Pharmaceutics™

Integrated Development Offering To Facilitate Adaptive Trials & Accelerate Phase 1

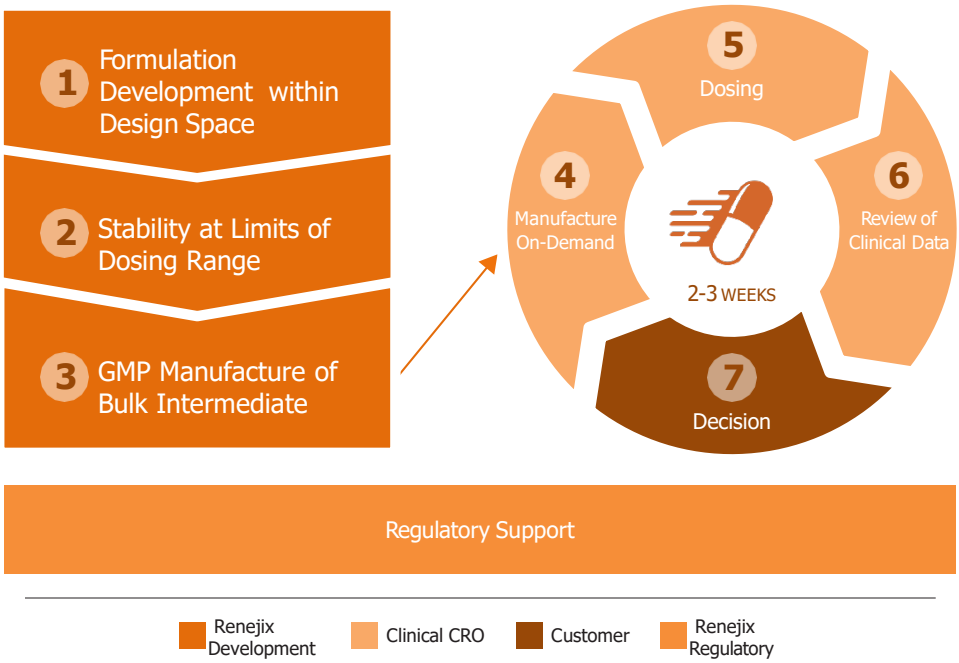
Revolutionize your Phase 1 Clinical Studies with Renejix Prime Pharmaceutics™. Stuck with inflexible dosing and slow progress? Our one-stop solution combines formulation, manufacturing, and regulatory support to bring you unparalleled flexibility. Adjust dosage and formulation in real-time based on clinical data, cut costs, and speed up timelines—all while using less API. Make your next First-in-Human study smarter, faster, and more cost-effective.

3 TO 5 MONTHS VS 9 TO 12 MONTHS TRADITIONAL CMC MODEL

Benefits of Renejix Prime Pharmaceutics™

- Quick to First-in-Human and proof of concept studies using on-demand product manufacturing close to the point of administration
- Utilizes scalable formulations for quick formulation and dose adjustments at the clinical site
- Significant savings on both API and time
- Allows better decision making using real time clinical data
- Integrated approach that supports customers' regulatory filing strategies

How Does Renejix Prime Pharmaceutics™ Work?



1. FORMULATION DEVELOPMENT Phase-appropriate, intermediate products are designed using a wide range of technologies, both simple or bio-enhanced (i.e., spray drying, hot melt extrusion or lipid-based); Mapping of the 'formulation design space' enables flexible choice of formulation, the dose, or both.
2. STABILITY OF GENERATED PRODUCTS AT THE LIMIT DOSING RANGE Sufficient 'in-use' stability is established in the intended presentation format (e.g, blend in capsules/ bottles) at the limits of the dose range to be evaluated.
3. GMP MANUFACTURE OF BULK, SCALABLE INTERMEDIATE Scalable, single-batches of intermediate formulations are manufactured and supplied for clinical testing.
4. ON-DEMAND MANUFACTURING AT CLINICAL SITE The bulk intermediate product is filled on-demand into capsules or bottles by the contract research organization's (CROs) Phase 1 Clinic.

5-7. ITERATIVE DOSING, REVIEW OF CLINICAL DATA, AND DECISION MAKING Dose increments are established based on emerging clinical data; Iterative cycles of up to three weeks between cohort dosings.

8. REGULATORY SUPPORT Focus on speed-to-clinic by identifying data that can be generated on non- clinical batches; Preparation of CMC section of regulatory submission with inclusion of justification for use of dose ranges, to allow rapid changes to dose during the clinical trial, alleviating need for interactions with the regulatory authorities

Achieve fast, flexible and efficient Phase 1 with Prime Pharmaceutics™

DRIVEN BY SCIENCE,
DEDICATED TO PATIENTS.™

Discover more solutions at renejix.com

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