

RareMoon

ORPHAN DRUG REGULATORY SERVICES

PROJECTS RELATED TO DRUGS & BIOLOGICS*

TYPE OF PRODUCT	INTENDED USE	SCOPE OF WORK
Small molecules/peptides	Lysosomal Storage Disorders	FDA
Nanomedicine	Muscular Dystrophies	Type B Meetings including pre-IND
Monoclonal Antibodies	Oncology (inc. solid tumors and blood cancers)	Breakthrough Designation
Cancer vaccine	Dermatological diseases	Fast Track
Immunotoxin	Hematological diseases	Orphan Drug Designation
Combination Product	Ophthalmic diseases	IND/CTA
Anti-infectives	Medical Countermeasure	Rare Pediatric Designation
	Infectious diseases	EMA
		Early Interaction
		Scientific Advice
		Pediatric Investigational Plan (PIP)
		Orphan Drug Designation
		Other
		IND/CTA/NDA (ICH) GAP
		Analysis
		Nonclinical development plan
		Clinical Development
		Synopsis
		Benchmark analysis
		Regulatory Roadmap

* Not reflective of experiences prior to RareMoon.