

Rare Disease Product Journey

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Rare Disease Product Journey



- Pipeline opportunity assessment with greater focus on disease prevalence
- Development of diagnostics and screening capabilities
- Licensing / commercially reasonable efforts disputes
- Patient safety and health equity assessment



- Market access and evidence generation strategy
- Payer value proposition
- Landscape assessment and policy shaping
- Pre-launch disease state awareness
- Interactions with patient advocacy organizations



- Launch pricing strategy
- Payer negotiation
- Launch excellence including continuing disease state awareness
- Stakeholder engagement and education, from HCPs to patient advocates
- Competitive simulations
- Quality, pricing and reimbursement policies
- Manufacturing and distribution



- Patient identification and finding including HIPAA/privacy considerations and genetic testing
- Indication and geographic expansion (expanded access programs)
- Patient compliance
- Pricing, access, and distribution ex-US, including FCPA/ABAC risk
- Competitor response strategies
- Loss of exclusivity strategies