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**Vorpal accelerates
access to life-changing
healthcare innovations**

End-to-end Solutions for Success in Japan's Healthcare Market

Strategy Partnering Execution

Innovation Research & Development

- Joint Development with Clinicians
- Intellectual Property Strategy
- Technology Transfer
- Biomedical Design
- Prototype Development
- Usability Confirmation
- Regulatory Compliance Confirmation

Opportunity Validation

- Patient Population Definition
- KOL Identification & Influence Mapping
- Treatment Landscape Clarification
- Product Evaluation
- Pricing Assessment
- Opportunity Sizing

Clinical Development

- Clinical Trial Design
- In-Country Clinical Caretaker (ICCC) Services
- KOL Engagement & Site Selection
- Clinical Operations & CRO Management
- GCP Compliance Assessments
- Post-Marketing Surveillance (PMS)
- Clinical Research Support

Regulatory Development

- Regulatory Strategy Formulation
- PMDA & MHLW Engagement
- KOL & Medical Society Engagement
- High Medical Needs & HBD Program Listing
- Orphan Drug / Device Designation
- Regulatory File Submission
- Q&A to Approval

Market Access

- Reimbursement Strategy Formulation
- Medical Society Engagement
- Patient Group Engagement
- Treatment Guideline Influencing
- MHLW Engagement
- HTA & Health Economic Analysis
- Reimbursement Application Submission
- Q&A to Acceptance

Quality & Operations

- QMS Development & Maintenance
- Designated Marketing Authorization Holder (D-MAH) Services
- Importation & Market Release
- Labeling & Repackaging
- Warehousing & Logistics
- Vigilance Management & Reporting

Commercial Development

- Marketing & Business Strategy Development
- KOL & Rising KOL Engagement
- Advisory Board Establishment
- Congress Strategy & Implementation
- Clinical Education Program Development
- Clinical Research & Publication Support
- Distribution Partner Selection & Engagement
- Business Incubation & Acceleration
- Sales & Distribution