



Client

Client is a leading Chinese In-Vitro Diagnostic Company with global distribution in North America, Europe and Asia.

Products

A Covid-19 Rapid Antigen Test (oral fluid)

Service Categories

- ✓ Regulatory Affairs
- ✓ Clinical Trials
- ✓ Quality Management System Implementation

Country of Interest

Japan / PMDA

Services Provided

- ✓ IVD Classification in Japan
- ✓ Preparation of Meeting with PMDA
- ✓ Clinical Study in Japan
- ✓ Foreign Manufacturer Accreditation
- ✓ Registration of IVD with PMDA
- ✓ QMS Registration

Key Highlights:

- ✓ Regulatory & Clinical Strategy Consultants with 15-35+ Years Experience
- ✓ 100% Approval Rate
- ✓ 3 Sites in Japan
- ✓ 300 Subjects

Keywords:

Japan, Radiopharmaceutical, Isotopes, Oncology, treatment, diagnosis, PMDA, FMA, PMDA consultation, J-NDA submission, medical writing.

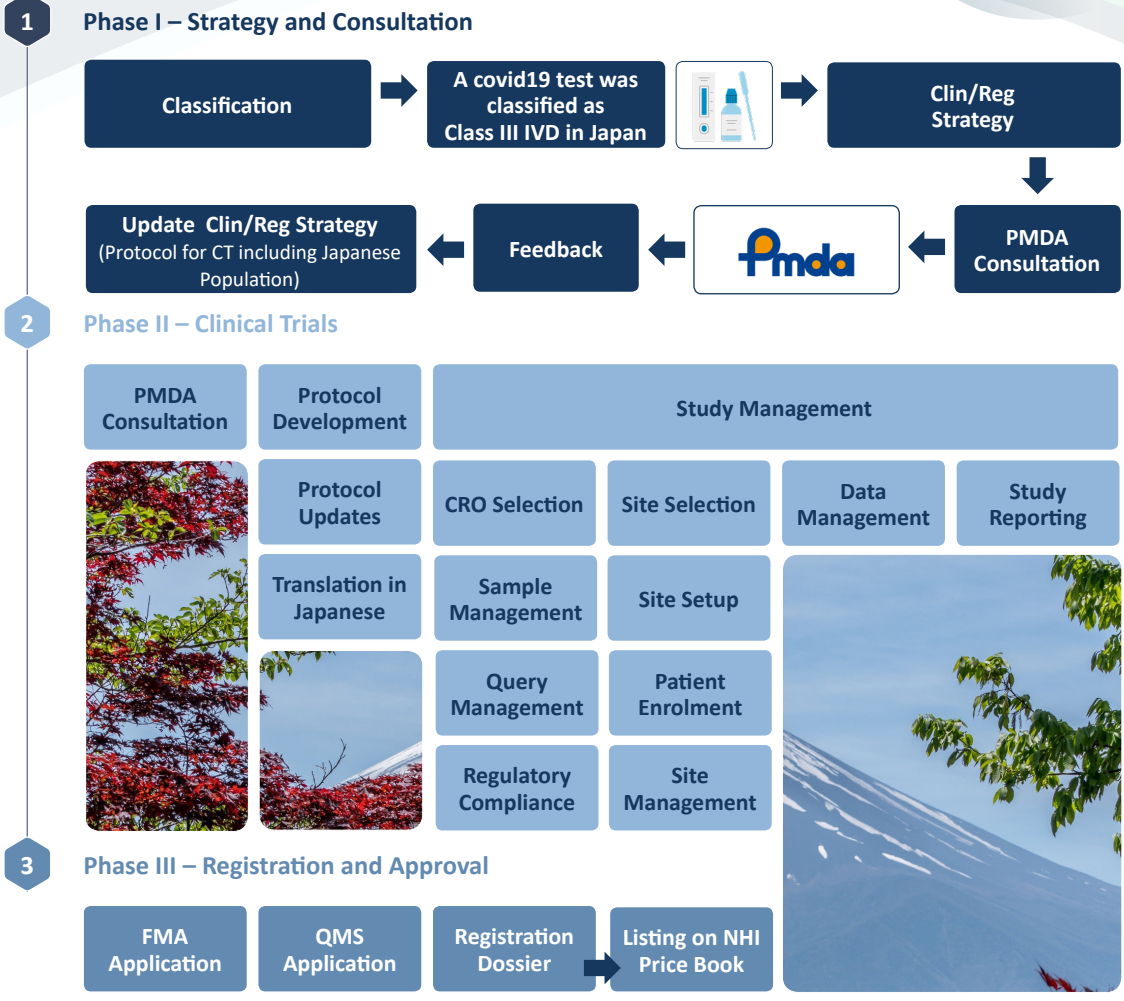
Client Situation

The Client was in the process of commercializing its new developed oral fluid based covid-19 rapid antigen test in global markets. Japan was one of the key markets for the client for strategic expansion. However, they did not have a regional presence nor any prior experience with PMDA. Considering stringent regulations in Japan and requirement for clinical trials, Client sought a strategic partner who could own the registration of their IVD device in Japan through the entire development phase and marketing.

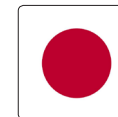
GRP Solution

GRP has successfully helped global corporations obtain approvals for their Covid 19 related IVD, pharmaceutical and vaccine products. Using GRP Japan's 30+ years of experience with PMDA, In-vitro diagnostics products and insights from Covid 19 tests, GRP stepped up as integrated partner for client to help them navigate through the development and registration phases of their product in Japan.

GRP's Multi-Stage Support from Strategy, Clinical Trials to Approval



Sample Import Assistance
 Warehouse Selection
 Custom Clearance



For additional information, please contact us at info@globalregulatorypartners.com