

# Global Meditech Market Clearance Consulting Service





# **Total Medical Service Consulting**

## Global Market Clearance Service

MEDITIP Consulting (Korea) guides you into the Korean and Global Healthcare market with intelligence, in-depth knowledge and experiences.

We have rich experiences in successfully collaborating with Global leading Bio technology supplier (Big-Pharma and Bigmedical device companies and Bioventure companies) for Korea and Global market entry issues, pre-market regulatory affairs, post-market compliance affairs, clinical trials, reimbursement pricing, local distributor identification, market feasibility study and government relations, etc.

MEDITIP is well connected with the key government authorities, local and global companies' decision makers to provide high quality of intelligence that is crucial to your business success in Korean and Global market.

# **Business Scope**



# Why Meditip?

#### Regulatory Affairs (MFDS)

## Strategic consulting

- Establish RA strategy(FDA, EMA, etc)
- Develop Synopsis of Clinical trial and Bridging study
- Review and Evaluation of IND/NDA and CTD
- \*Total over 50 projects and 5-15 projects/year

#### 2. Preparation of Application doc

- Preparation of submission package for MFDS Application
- \* Total over 150 projects and 10-15 projects/year

#### 3. Monthly consulting service

#### Global Registration

- Strategic consulting collaborating with global partner
  - Establish RA strategy(FDA, EMA, etc)
  - · Develop Synopsis of Clinical trial
  - Review and Evaluation of IND/NDA and CTD
  - \* Total over 10 projects and 2-3 projects/year

#### 2. Preparation of Application doc

- Preparation of submission package for global registration
- \* Total over 10 projects and 2-3 projects/year

### Health Insurance

#### 1. Strategic consulting

- Estimation of price and reimbursement range
- Interview and/or Getting opinion of Health Insurance authorities
- Re-evaluation of PE or Non-direct comparison
- HTA/Korea CPT coding
- Total over 15 projects and 3-5 projects/year

#### 2. Preparation of Application doc

- Preparation of Application form and related data
- \* Total over 6 projects and 1-2 projects/year



EvaluatePharma incorporates all the data required to fully analyze, understand and derive values from the pharmaceutical and Biotechnology industry.





