## **Why MediHelpLine**

## CRO providing Real Total Package Service

- Ultimate Partner from Development to Market Approval for Your Product

  Proven record over 80 RA projects per year, MediHelpLine helps expedite your product launched in the market from the very start of development till the market approval in the most effective way.
- Not Only Pre-NDA Studies(Phase I ~ III) But also Follow-ups for Post-NDA Activities

  MediHelpLine provides comprehensive services from Pre-NDA studies to Post-NDA studies such as

  PMS, NIS, PASS with proactive management for the highest level of quality, safety and efficacy.
- In-house Data Management & Bio-statistics Department for Your Quality Data

  MediHelpLine's in-house DM & BS departments provide study design set-up,
  data validation & management, data verification, coding, CDISC, high quality QC system.

  It's EDC system covers medidata( #medidata), cubeCDMS(cubecDMS\*),
  BETHESDA SOFT( \*\*\* BETHESDA\*\*), Viedoc( Viedoc \*\*\*\*) in order to meet global standards.



Your Gateway to the World Market from Regulatory Affairs to Clinical Trials

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### **OUR MISSION & VISION**

#### **OUR MISSION**

MediHelpLine Co., Ltd. Contributes to the development of the healthcare industry by providing high quality services, which come from our specialized knowledge and profound experiences. We help our client in creating success and prosperity by expeding its product development and registration. We strive unceasingly to be the unquestioned best partner with our customers in Korea.

#### **OURVISION** /

To structure one-way total solution for meeting global clients' needs in healthcare industry by 2020.



## **SERVICE SCOPE**

#### **REGULATORY STRATEGY AND SUBMISSION SERVICES**

Build strategies that meet the demands for dynamic regulatory environments in global and local market

#### **NEW BUSINESS FOR GLOBAL MARKET**

Strive to attain global competitiveness. We build strategies meeting global customers' needs and organize CRO consortium

#### **CLINICAL TRIAL WITH IMMEDIATE AND DETAILED INSIGHT**

Proactive management for the highest levelof quality, afety and efficacy in monitoring, data management, statistical analysis, medical writing, etc.

#### **LATE PHASE STUDY SPECIALISED KOREA REGULATIONS**

Comprehensive services for PMS, NIS, PASS as well as Post-NDA studies

# THRIVING TO WORLDWIDE



**REAL** 

**TOTAL** 

**PACKAGE SERVICE**