# Accelerated Clinical Development & Market Access

## CLINICAL DEVELOPMENT

- Development Plan
- Study Planning & Design
- Medical Writing
- Project Management
- Clinical Trial Applications
- EDC, Data Management & Statistics
- Clinical Monitoring
- Clinical Safety & Medical Monitoring

## REGULATORY STRATEGY

- Designing Regulatory Strategies to Accelerate Product Development
- Hands-on assistance in implementation
- Scientific Advice
- Meetings with payers for product reimbursement

## MARKETING AUTHORIZATION

- MA dossier audit (Gap Analysis)
- Dossier Development
- PL Readability Testing
- MAA (CP/DCP/NP)
- Hands-on assistance during dossier assessment period

## POST-AUTHORIZATION SUPPORT

- Regulatory Support in MS
- Full Scope PV service
- QPPV & EV
- RMP & PURs
- Fully E2B M2, 21 CFR Part 11 compliant Safety Database
- PV Consultations
- Local safety representation