

Clinical & Economic Evidence and Value Demonstration

*Optimizing price,
reimbursement
and formulary
access decisions
for your
products*

INTEGRATION OF PROJECTS INTO COMMERCIAL AND REIMBURSEMENT CONTEXTS

- > Planning and alignment of evidence generation with the product's profile, internal timelines and targeted audience.
- > Perform competitor review, evidence gap analysis and propose tailored solutions.

STRATEGIC INSIGHT

- > Fourteen senior directors with decades of experience in industry, academia, consultancy and regulation.
- > Two internal advisory boards composed of eleven experts in the field of pricing and reimbursement and health technology assessment.

TAILORED SOLUTIONS

- > Evidence synthesis (meta analysis), indirect treatment comparisons and comparative effectiveness.
- > User-friendly cost-effectiveness and budget impact models [Decision analytic, (semi) Markov state-transition, dynamic and infectious disease, patient simulation, and comprehensive decision models].
- > Generation of utility evidence (direct utility measurements: time trade off / standard gamble).
- > Burden of disease, cost of illness, and database analyses.
- > Design of case report forms and analysis of economic data from clinical trials.
- > Workshops on indirect treatment comparisons, value of information analysis, and direct utility measurement.

VALUE COMMUNICATION

- > Develop global value dossiers and country-specific reimbursement, pricing and HTA dossiers.
- > Prepare for reimbursement submissions and successful launch with value arguments tailored to the target audience (NICE, SMC, CVZ submissions).
- > Provide comprehensive post-launch clinical & economic evidence support by using effectiveness evidence, economic data/models and value messaging to ensure continued market access.

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Patient Reported Outcomes and Value Demonstration

*Ensuring valid
and meaningful
endpoints to
differentiate
your product*

INTEGRATION OF PROJECTS INTO COMMERCIAL AND REGULATORY CONTEXTS

- > Planning and alignment of PROs with the product's profile, clinical program, international scope and targeted audience.
- > Outcomes and evidence generation strategies, instrumentation, timing, and analysis methods.
- > Perform competitor review and evidence gap analysis and propose tailored solutions.

STRATEGIC INSIGHT

- > Fourteen senior directors with decades of experience in industry, academia, consultancy, and regulation.
- > Networking with regulatory agencies (FDA, EMEA, PMDA and Thai FDA) and routine monitoring of recent regulatory decisions and requirements.
- > Assistance in planning regulatory encounters with the FDA and EMEA, and in developing and responding to regulatory correspondence.
- > Development and/or revision of labeling and promotional claims language.
- > Attendance at regulatory meetings (e.g., IND and Type C meetings) and mock FDA meetings.

TAILORED SOLUTIONS

- > Development of patient reported outcome measures:
 - Primary or secondary endpoints for labeling and promotion: symptoms, functional impact, health related quality of life, satisfaction and preference.
 - Diagnostic and screening tools for clinical research and clinical practice.
 - Individual tools to evaluate goal achievement, adherence and persistence.
- > Patient focused qualitative research.
- > Psychometric validation (classical, item-response theory, Rasch analysis).
- > Analysis of PRO endpoints in clinical trials.
- > Workshops on PRO regulatory issues and PROs in drug development.

VALUE GENERATION

- > Development of briefing documents for submission to the FDA and EMEA.
- > Communication on the clinical relevance and the value for patients of the PRO measures.
- > Incorporation of PRO messages into market access (global value dossiers, formulary submissions and communication plans).