Every patient receives what she or he needs

VISION & MISSION

OUR VISION:

Every patient shall have a fast access to the best possible therapy at a fair price.

OUR MISSION:

SmartStep offers specialized and individualized consulting services for the pharmaceutical and medical technology industry to achieve or maintain a fast and broad Market Access for the products.

BASIS OF OUR WORK:

SmartStep focuses on the very complex and highly regulated German and European health care market and quickly and dynamically develops convincing strategies for all phases and challenges of Market Access. For national and international medical technology manufacturers, who seek guidance for the implementation of new regulatory demands as well as a fast and extensive Market Access at a fair price or strive to maintain an adequate price in their existing market, SmartStep is the consulting company of your choice. The foundation of SmartStep's competence is the long-time experience working in the national and international health care industry and with all relevant key stakeholders – therefore SmartStep not only performs tasks, but excels at delivering solutions.

Specific, measurable, attractive, reachable, timed solutions

SMART

SmartStep Consulting is a team of more than 30 seasoned professionals with a wide array of scientific and industry expertise. Dr. Timm Volmer, MPH, founded SmartStep Consulting GmbH in 2010, specializing in Healthcare and Market Access Consulting, following his 17-years tenure in the industry. A wide mix of professions including pharmacists, biologists, health care professionals and engineers as well as statisticians belong to a young and motivated team to support your products.

SMART STEP

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Healthcare Strategy & Market Access

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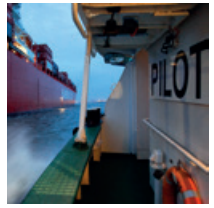
Make your next move SMART

BE PREPARED

SMART STEP

SmartStep offers highly specialized and individualized consulting for the pharmaceutical, vaccine, biotech and medical device industry to accomplish, defend or sustain a fast and efficient Market Access for your products.

HEALTHCARE STRATEGY



MARKET ACCESS & NEGOTIATION

STAKEHOLDER MANAGEMENT

Ranging from simple sticking plasters and contact lenses to sophisticated pacemakers and hip replacements, medical devices and in vitro diagnostic medical devices are important to our health and quality of life. People rely on these devices every day and expect them to be safe and incorporate the latest progress in science and innovation.

European Commission

EURPOEAN MEDICAL DEVICE REGULATION

The MDR will demand a whole new level of data quality for the evaluation, processing and presentation of risks and benefits of medicinal products and health technologies. For new as well as established medicinal products additional data with high level of evidence has to be generated in order to grant or sustain CE certification. This process can take several years, depending on the risk class of the product. So better start now and be prepared.

GERMAN MARKET ACCESS FOR „NEW EXAMINATION AND TREATMENT METHODS"

The Market Access for „new examination and treatment methods (NUB)" in Germany is regulated and supervised by the Federal Joint Committee (G-BA). Innovative medicinal products have several routes through the assessment system, depending on setting – ambulatory or hospital – and risk class. NUBs with high risk medicinal products will be assessed according to § 137h SGB V, whereas other NUBs will be subjected to §§ 135 and 137c.

The G-BA will not only assess new methods based on existing evidence. For products with insufficient data but high potential it will also have an active part in planning and financing a testing phase inside the German health care system and assuring reimbursement at the same time during testing. This reflects the German interpretation of the global mega trend for more evidence in reimbursement decisions of health technologies.

WHAT WE CAN DO FOR YOUR PRODUCTS:

- ✔ Reimbursement of new products inpatient and outpatient, e.g. by NUB applications, DRG work-shops, applications for OPS codes
- ✔ Development of advice requests to authorities, notified bodies and expert panels
- ✔ Preparation of internationally harmonized / coordinated Market Access strategies,
- ✔ Analysis of reference pricing
- ✔ Contracting models with payers and insurance companies
- ✔ Development and performance of 'Sounding Boards' for fruitful discussions with decision makers
- ✔ Development of stakeholder management strategies
- ✔ Negotiations during the Market Access process with perfectly matching contacts
- ✔ Customized training for oral hearings and statements
- ✔ Support during the process of negotiations and decision making.
- ✔ Monitoring and evaluation of results and measures

Make your next move smart

SMART STEP

Assessment procedure according to § 137h SGB V

For „new examination and treatment methods (NUB)" with high risk medicinal products (IIb and III which are highly invasive) with new theoretical-scientific concepts