Successful in Europe

Comprehensive Service for

European Market Entry

by Experienced Local Experts



<u>The European Challenge – and our Solution</u>



- Europe poses considerable challenges for new entries due to:
 - 28 countries with 28 different healthcare systems
 - Different pricing and reimbursement regulations
 - Different treatment protocols and practices
- To that end, investments in the European markets pose significant risks for investors, the company, as well as for all other stakeholders
- While evaluating an investment or taking the first steps towards market entry, critical information and insights based on real life experience are invaluable but difficult to obtain
- We are a team of experts bringing together years of experience in the European marketplace and complementary know-how – that can support your product launch / market entry initiative
- We may help prepare and orchestrate your market entry with our knowledge and expertise and thus provide support to succeed

Successful in Europe - How we may Support you to Succeed



- Proven track-record and in-depth knowledge of the key European markets (more than 100 projects)
- Repeated involvement with growth-stage and established companies prior and during the European market entry stage
- Pharma, Biotech, Diagnostics/IVD and MedTech
- Information sources available for providing fact-based decision support regarding quantitative (market size) and qualitative (market access) topics
- Analytical tools available off the shelf or customized for planning, forecasting and sales projections
- Key personnel with +20 years experience as consultants within the local and global healthcare markets
- Located in Germany (most important European market) with local US presence
- Additional network of healthcare experts for special demands (more information: www.healthcareshapers.com)

Support to Success



Sales Potential / Forecasts

Market model based on robust bottom-up data to project sales potential and develop forecast scenarios

Launch Preparation

Hands-on support to build country organization (stand alone, partnering) across main EU countries

EU Strategy Clinical Development

EMA Approval Launch Preparation

Market Launch

EU Strategy Alignment

Alignment of US/EU strategy considering different markets, customer segments, and other country-specific requirements

Clinical Trials Support

e.g. Clinical development plan, clinical trails design, clinical trail realization

Support to Succeed - EU Strategy Alignment

EU Strategy Alignment

Alignment of European to the global (US) strategy by considering the subtleties of the different markets regarding:

- country-specific requirements
- Patient specifics, customer segments
- Patient flow, treatment settings and preferences
- Prescriber / customer preferences and behavior
- Competitive situation
- Regulatory/other market specific requirements

In addition particular topics regarding market access, pricing and reimbursement processes will be addressed.

Development of market entry strategies, e.g. ranging from stand-alone concepts to partnering (or out licensing) solutions.

Support to Succeed - Sales Potential

Sales Potential / Forecasts

Beginning at an earlier stage of development until pre-launch phase, we develop comprehensive models, based on hard data (such as true patient numbers, epidemiological data, procedures, etc.) in order to provide reliable models for:

- Projecting sales potential and forecasts for different EU markets
- Evaluate different product positioning strategies on their probability of success
- Calculate net present value, NPV, or model ROI of marketing investments
- Conduct portfolio optimization across multiple assets (e.g., products, development projects, therapeutic areas). Allocate resources across different markets, products, geographies

Data will either be warehoused in an Excel format or within a proprietary Online-Platform.

Support to Succeed - Clinical Trials Support

Clinical Trials Support

We provide support during the clinical trial phase from overall preparation of the clinical development plan to clinical trials support, e.g.:

- Outline clinical development plan
- Elaboration of clinical studies
- Support to execute clinical studies

In particular, we assure that specific European requirements concerning market access topics, such as benefit appraisals, etc. will be addressed in the clinical development.

Most notably, this ranges from selecting the proper clinical endpoints that are typically accepted by the national agencies to providing the right data for the development of cost-effectiveness models.

Support to Succeed - Launch Preparation

Launch Preparation

We will assist during the pre-entry phase and go-to market activities, such as:

- Setting up internal country/EU organization
- Develop go-to market plan
- Support market access activities
- Elaborate partnering models

Other activities to start a successful EU/EU country business including, but not limited to:

- Marketing and Sales strategy
- Target identification and targeting plan
- Sales force training
- Ad Board / KOL Speakers / educational program development
- PR and Publication strategy

Your Team to be Successful in Europe





Christian Neckermann

is based in Boston, Mass. and has been working in the healthcare field for over 20 years to facilitate decisions that drive growth and profitability. Christian has vast international background and firsthand experience working across several continents. Christian is founder and president of Cogent Consulting.

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Prof. Dr. Thomas Teyke

is based in Cologne,
Germany, and is Associated
Partner with Cogent
Consulting. He has extensive
consulting experience within
the key European countries.
In addition to his consulting
work, he is Professor for
Health Economics and
Dean/Program Director at
Hochschule Fresenius
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Sciences.



Dr. Rolf Porsche

is based near Munich and has more than 20 years of consulting, experience. He is a trained Physician with working experience on the board level from global healthcare companies to start-ups. Rolf is founder and director of PorscheHealth.

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