IGES IJFE SCIENCE

from information to innovation

IGES LifeScience

Research and consulting for developers, investors and manufacturers of innovative healthcare products.

Comprehensive Approach from the Start

Since its foundation in 1980, IGES has been committed to focusing on objective perspectives in its work, through which it has attained a profound understanding of all players in the healthcare sector and developed consistently high levels of credibility across the board. This 360-degree approach is paramount for patients to optimally benefit from novel, and sometimes completely unknown, therapies and products. Regulators, payers, physicians, healthcare institutions and patients must be certain that the therapies and products in question are based on the best possible scientific and economic evidence.

From Information to Innovation

IGES has always been working with big data. Its broad access to data has been almost unparalleled to date. We have never considered research and development to be an end in itself, but consistently focus on maximizing the benefits for the population.

In this tradition, IGES LifeScience has focused on determining optimal conditions for different therapies - pharmaceutical, medical and digital - in order to achieve optimal outcomes for both the patient and society.

Against this background, IGES is in a position to conduct all the necessary analyses required over a product's entire life cycle and to support optimal decision-making during the consultation process.

The European Perspective

A successful strategy in Europe must be based on the fact that very different regulations exist in the individual countries and it must also take into account the fact that processes to harmonize these have also already been set in motion.

We bring together a creative group of European companies so as to achieve the best possible outcomes when it comes to market access and reimbursement.

Pharma Strategy

The question of how a novel therapy can be optimally positioned within a specific national market is addressed differently by different national healthcare systems. This is the only means by which both the manufacturer and all stakeholders involved can ensure that they strike a fair balance with regard to their expectations. This process not only includes having a precise knowledge of national regulations but also demands optimal planning of the scientific programmes used to deliver the results required for different phases of a novel drug's life cycle. Dialogue with payers and other stakeholders as well as knowledge of national evaluation systems and markets are essential.

Horizon Scanning

> Stakeholder Engagement

Market Access Strategies



Pharma HTA

The health systems of the individual EU countries face the challenge of providing patients with access to new treatment methods within their limited budgets. The evaluation of the added value of an innovation is becoming more and more important and is carried out from the perspective of the various political and social structures of a country. Methods of Health Technology Assessment (HTA) are used. The results determine the reimbursement of new products and thus their financial impact on a health-care system. Notwithstanding Europe-wide efforts to harmonize HTA methods, knowledge of country-specific pricing and reimbursement regulations will continue to be important.

Early Strategic Support

Dossiers: AMNOG, NICE, HAS

Comprehensive Support in all HTA Phases

Reference Price Management



Real World Evidence & CRO Services

Real world Evidence (RWE) results from the evaluation of data obtained in real healthcare situations. In addition to clinical studies, it is becoming increasingly important to answer scientific questions regarding new therapies. RWE has therefore become an essential tool to demonstrate the value of a new drug in the context of approval and benefit assessment. Once a new treatment has arrived in everyday care, RWE helps to show the perspective of patients and the impact on professional care, which is relevant for insurance funds. RWE's generation requires a precise overview of which stakeholder needs which information at which point in time. Planning and efficient implementation of such studies is essential and is supported by close cooperation with a CRO.

RWE Data Synthesis

Observational Studies: Prospective & Retrospective

Machine Learning Tools

Early Epidemiological Assessment



Health Economics

Economic as well as clinical aspects must always be taken into account when making decisions about market access and negotiating pricing of therapies. The main challenge is to extrapolate data from small study populations with a short study duration to cover the entire population over a much longer period of time. In this context the use of health economic models is crucial for obtaining satisfactory results, but only possible in the hands of experts.

Cost-Benefit Assessment

Health Economic Strategies

Budget Impact Analysis

Health Economic Evaluations & Modeling

Cost-Effectiveness & Cost-Utility Analysis

Medical Technology

Medical devices play a central and ever increasing role in health care. They contribute to making health care more efficient. The market launch and reimbursement of new developments in medical technology are subject to increasingly complex regulations. This is due to the greater demands on proof of benefit and safety in view of the limited budgets in the various healthcare systems. A precise knowledge of the national health markets is therefore a prerequisite for successfully introducing medical devices into everyday medical care.

Publication & Communication



HTA & Value Demonstration



NICE & GBA Guidance & Implementation

Local, National & Transnational Market Access

Reimbursement

Digital

Value Story

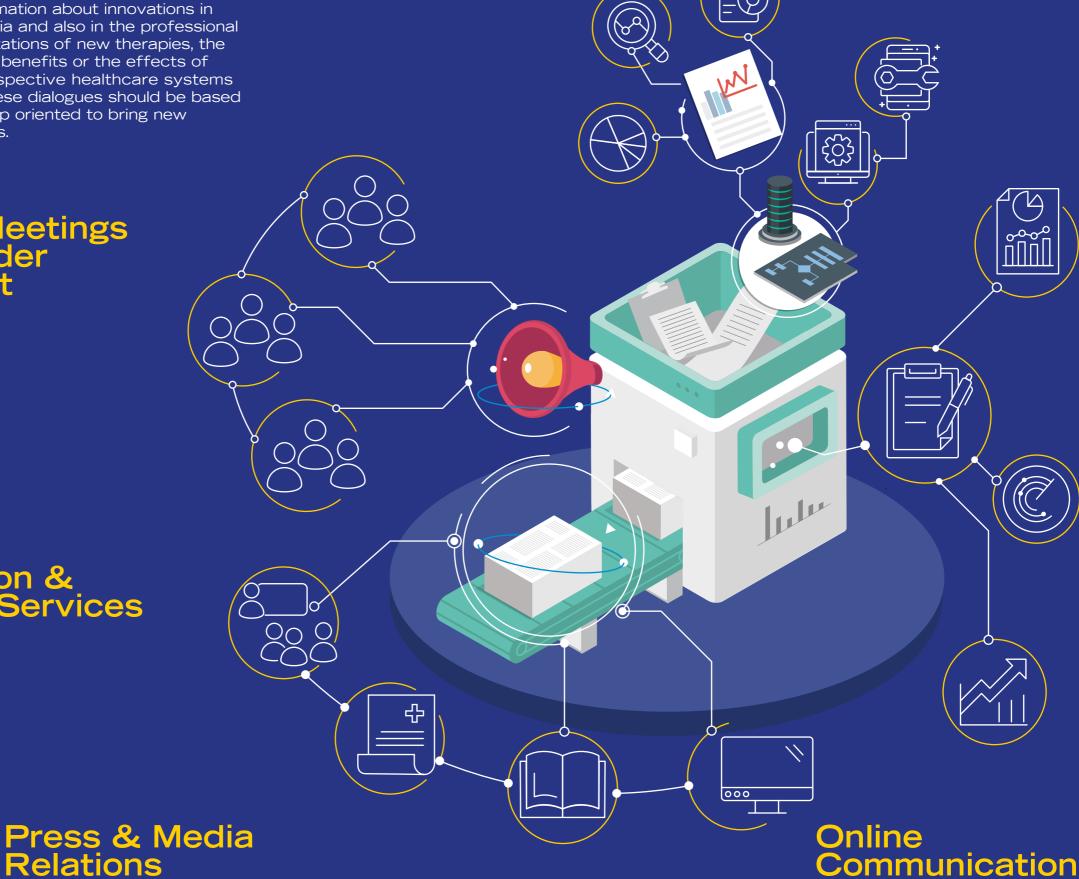
Healthcare systems expect considerable efficiency gains and a closer patient orientation in medical care Evidence Generation from digitization. In Germany, market entry is supported by the Digital Care Act (DVG). Entry into the healthcare market opens up the opportunity for reimbursement by health insurance funds, but increases the requirements for the effectiveness and safety of digital products. Their proof is based on established standards for evaluation procedures for pharmaceuticals and med-= 🗆 = 🗹 ical devices. Precise knowledge of these procedures = - is therefore the basis for a successful market entry strategy for innovative digital health products. Market Access DiGA Health Care Compass Q ••• Digital Care Act Handling

Communication

Communication about new treatment methods has become increasingly important in recent years due to the enormous scientific progress. This is reflected in the exchange of information about innovations in everyday life, in the media and also in the professional context. Patients expectations of new therapies, the developers' promises of benefits or the effects of new products on the respective healthcare systems are often discussed. These dialogues should be based on facts and target-group oriented to bring new insights to all participants.

Scientific Meetings & Stakeholder Engagement

Publication & Editorial Services



Communication Planning

IGES Group

Experts for the Life Science Industry

Independent and innovative: The IGES Group focuses on research, development and consulting for health and healthcare in Europe.

Members of the IGES Group include different multiprofessional research and consulting companies based in different countries, which have united to form a global network and offer a joint portfolio for international services.

GES

Healthcare Research

The IGES Institute is the core of the IGES Group. It was founded in 1980 and has become one of Germany's most important voices for research, consulting and development of healthcare. It offers comprehensive services based on advanced expertise including: studies, reports, publications, evaluations, concepts and strategies.

Wioletta Kotowa

Director of Health Economics & Outcomes Research wioletta.kotowa@iges.com

Fabian Berkemeier

Director of Value & Access Strategy fabian.berkemeier@iges.com

CSG

Clinical Trials

CSG (Clinical Study Group) is a full-service contract research organization, offering services in planning, implementing, conducting and analyzing clinical-scientific studies.

Dr. Marc Kurepkat

Operating Director marc.kurepkat@csg-germany.com

Device Access

Medtech-Market Access

Device Access UK Ltd is a UK reimbursement specialist and provides health economic and strategic services for international medical device manufacturers focused on launching products to both the UK private healthcare market as well as the publicly funded National Health Service (NHS).

Michael Branagan-Harris

Chief Executive Officer mike@deviceaccess.iges.com

IMC clinicon

Data-Based Expertise for Hospitals

IMC clinicon is a consulting and services institute for the hospital sector, providing in-depth data and analysis on German hospitals.

Sebastian Irps

Managing Director sebastian.irps@imc-clinicon.de

AiM

Medtech-Reimbursement Support

AiM (Assessment in Medicine) is a health economics consulting agency for the medical device industry, focusing on reimbursement programs. Health technology assessment dossiers are founded on qualitative and scientific methodologies.

Michael Weisser

Chief Executive Officer michael.weisser@aim.iges.com

HealthEcon

Healthcare Consulting

HealthEcon, based in Basel, Switzerland is a consulting firm for health technology assessment, European market access and value strategy for the pharmaceutical industry, with almost 40 years experience.

Dr. Stephan Ruckdäschel

Managing Director sruckdaeschel@healthecon.com

MEDITECH ACCESS

Meditech Access

Meditech Access is a French consulting firm for the medical device industry based in Versailles. The company specializes in developing market access and distribution strategies for medical devices in the countries of France, Belgium and Switzerland.

Michel Verhasselt

Chief Executive Officer verhasselt@mtac.iges.com

Preferred partner

OPTIMAX access

dealth Economics

Optimax Access Ltd. is a Health Economics and Outcome Research (HEOR) consultancy based in the UK. They employ a multidisciplinary team of experts to work on developing value stories, as well as pricing and reimbursement strategies for pharmaceutical and medical device companies.

Dr. Mehdi Javanbakht

Director info@optimaxaccess.com

Realization infographics by Ellery Studio, Berlin

IGES Institut GmbH

Prof. Dr. Bertram Häussler Chairman of the Board of Management

Friedrichstraße 180 D - 10117 Berlin Germany

T +49 30 230 809 - 42 F +49 30 230 809 - 11 lifescience@iges.com

www.igeslifescience.com