

HANNOVER | APRIL 2024

SKC – who we are and what we do.

Company presentation

PREPARED FOR:

Pharmaceutical and biotech companies

PREPARED BY:

SKC



We are the market access special forces.

We are enthusiastically committed to solving demanding situations. We are the Market Access Special Forces.

Who we are and where we come from.

Established

2005

Intellectual Roots

The Boston Consulting Group

Institute of Epidemiology, Social
Medicine and Health Systems
Research at Hannover Medical School
(MHH)



Team 40+
Science grads 30+
PhDs 10+

with diverse backgrounds
in health economics, life /
social/ medical sciences,
pharmacology and full
support from the back
office and research team.



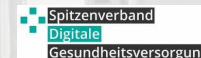
Network

tight cooperations to clinical
and scientific colleagues at the
MHH and other top-notch
medical institutes, to the payer
organisations and authorities.

Member of



BPI Bundesverband der
Pharmazeutischen Industrie e.V.



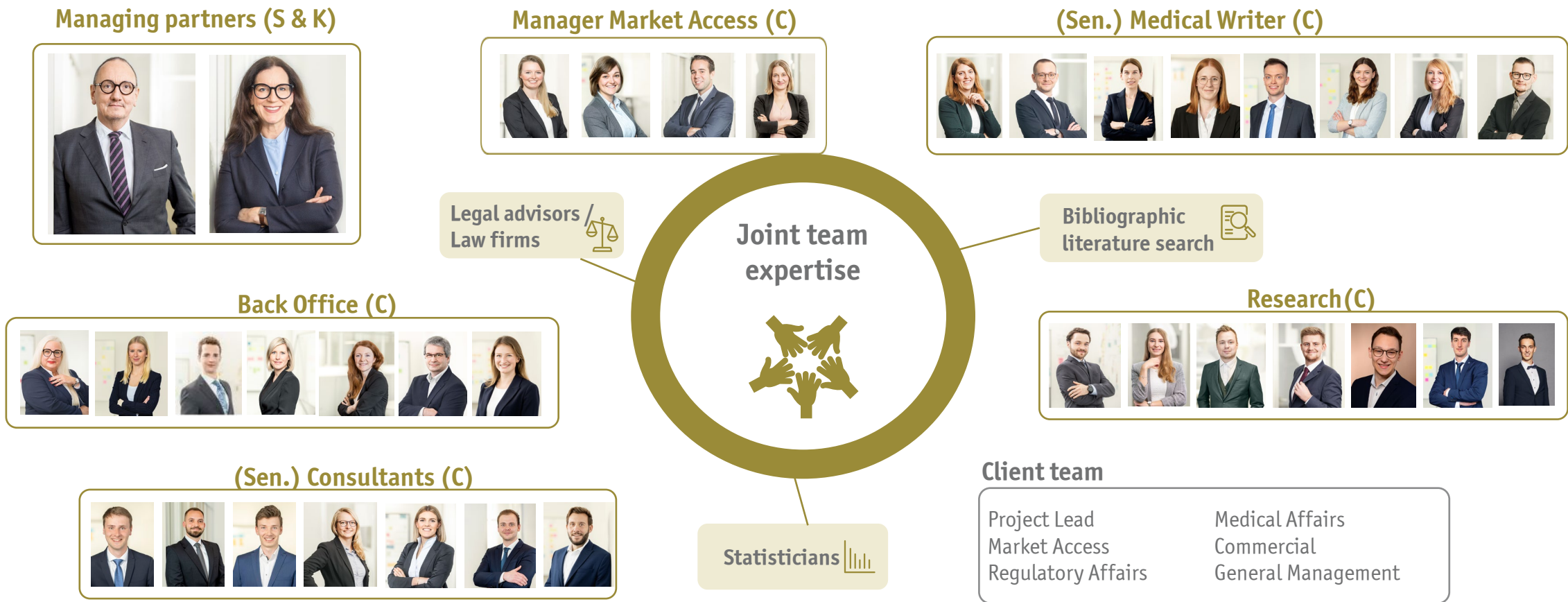
based in Hannover,
Germany with
connections to
healthcare
consultancies all over
Europe.



International

With our senior team and specialist network we ensure excellence and high quality.

Who we are.



Our projects are always a joint team effort with one main point of contact for the client.

Our mission drives us forward.

Mission



SKC's mission

To facilitate that patients with diseases for which no or only limited treatment options are available, receive access to effective treatments.

To ensure that as many eligible patients as possible are treated with an adequately reimbursed new product.



We assist our clients in answering their questions and solving their specific problems with our enthusiasm for health care.

Who we work for.

Our clients

Pharmaceutical companies

Biotech companies

MedTech

Digital Pharma

Investors / Venture capital

**We are the market access special forces:
strategic challenges are our specialty.**



Orphan diseases

Products indicated for orphan diseases: newly launched, reaching the 30 mio. € threshold, without orphan designation.



ATMPs

Gene and cell therapies, and tissue engineering products, which represent a paradigm shift in health care.



Repurposed drugs

Launch of existing drugs in new innovative indications.



Products altering the treatment paradigm

Products which do not fall under the other categories but still have a major impact on the treatment paradigm.

We are your Sherpa and Pathfinder and guide the way through the complex market access landscape.

How we work.

Our approach

Systemic

Patient-centered – we start with the clinical reality

We think from the finish line – what happens during the negotiations?

Agile – we have the normal VUCA in mind

What can you expect when working with us?



Tailor-made solutions

Even though we use a standardized approach every product and client is unique.



Honest, direct partnership

Strategic sparring partner challenging existing perceptions and hypotheses. Joint decision making is key. Regular exchange and full transparency.



Ownership

We make the challenges of our clients to our own. Hands-on mentality.



Humor

A good working-atmosphere for short and long-term projects is essential.

Our knowledge of the health care system is comprehensive and extensive - similar to our broad service portfolio.

Our services and core expertise



EUHTA: JCA90 and JSC

Mastering EU HTA with holistic strategy, convincing evidence, PICO evaluation and dossier compilation.



Full market access support

Hands-on operative and strategic management of the complete process.



Strategic due diligence

Strategic, hypothesis-based analysis of market potentials and business opportunities.



Strategic pricing

Defining well-balanced prices in a complex reference price setting.



Market access strategy

Development of best possible strategies for a successful and sustainable market access.



Digital Health Applications (DiGA) & Digital Pharma

Enabling "Beyond the pill" innovations to successfully enter the German market.



Value Dossier

A successful benefit assessment with a convincing value story



Benefit assessment (AMNOG, §35 SGBV)

Strategic management and leadership of all HTA challenges.



Negotiation support

Coaching, moderation and/or leading of negotiations and arbitration processes.



Stakeholder management

Identification, activation und integration of all decision-relevant stakeholder groups.

Source: Please visit <https://skc-beratung.de/services/index.php> for the latest overview

The MAIS database contains all relevant information related to G-BA's benefit assessments according to §35a SGB V.

SKC MAIS database



SKC's proprietary MAIS database

- enables us to analyze almost all parts of the G-BA procedure from start to finish **per indication, therapy area, pharmaceutical company, year, ...**
- enables **thorough precedence analysis**:
 - comparative therapy: costs, ...
 - study arms: control, population, duration, dosage, ...
 - endpoints: category, classification, instrument, acceptance, ...
- **enables price and rebate analysis** over time: based on price of the resolution, price before and after negotiation (based on Lauer Taxe) and the current price all relevant rebates are calculated

MAIS = Market Access Intelligence System

The database does not only provide an excellent overview of each procedure, it enables the link between AMNOG procedure and rebate development.

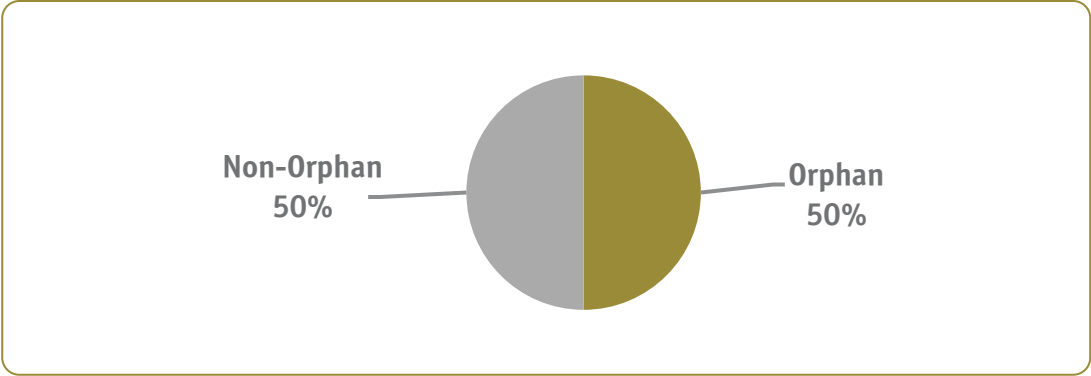
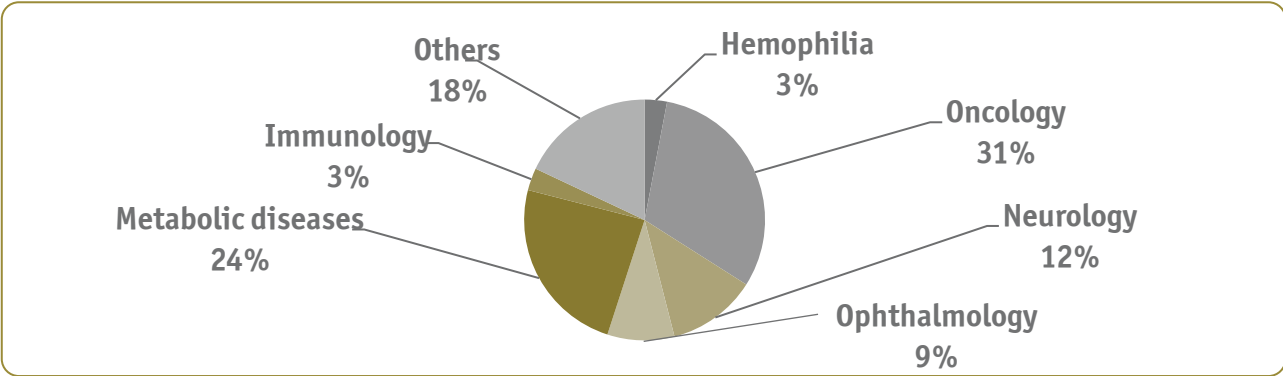
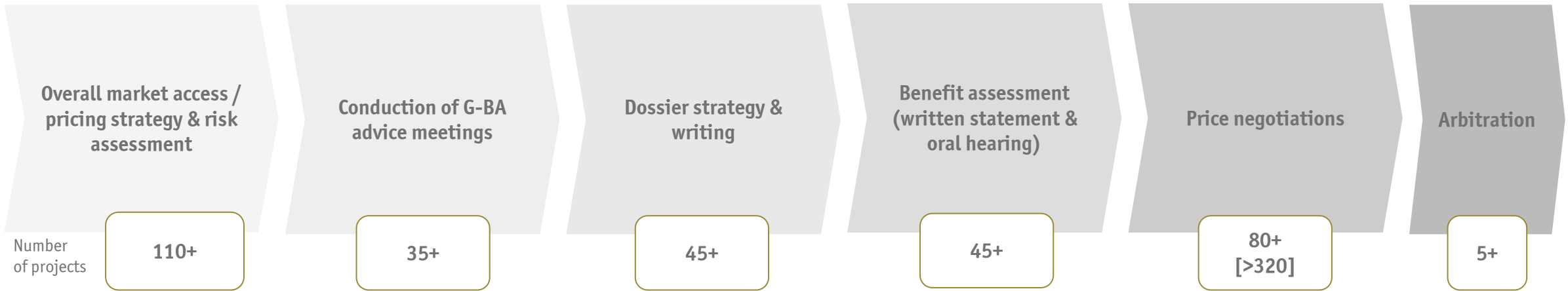
Source: SKC



We have a broad experience in all phases of the AMNOG process as well as in a wide variety of indications.

SKC expertise: AMNOG process

Completed projects



All our projects taught us that a well-defined strategy is essential for a successful completion of the AMNOG process.

Source: SKC project experience as of January 2024.



We are the 1st choice in the field of rare diseases.

SKC expertise: orphan drugs

Holistic understanding of strategic challenges



- The **rarity is only part** of the overall picture.
- It is about **successful market entry at the desired price level**, despite complex clinical pictures, late diagnoses, barely developed networks, limited evidence, a lack of RWE, special price expectations, major uncertainties in budget impact and **dwindling orphan privileges in the German system**.
- As Market Access Special Forces, we are familiar with the typical challenges and meet them with individual **solutions**.

Excellent relationships with relevant stakeholders



Numerous ZSE -
Centers for Rare
Diseases



¹ ~95 different drugs have undergone the AMNOG for the first time since 2016, with a total of >200 procedures including extensions etc.

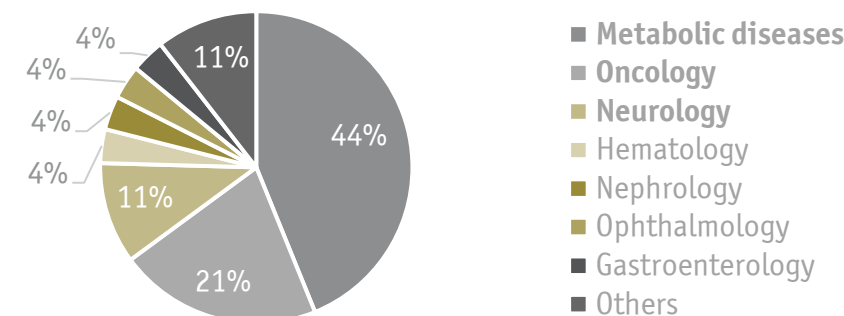
² Net annual treatment cost discount, only first submissions with negotiated discount from the Lauer tax until the end of 2023, only orphan drugs, SKC involved in the project or fully leading; t-test p = 0.0491

Source: SKC experience at the end of 2023



Successful and experienced in all indications

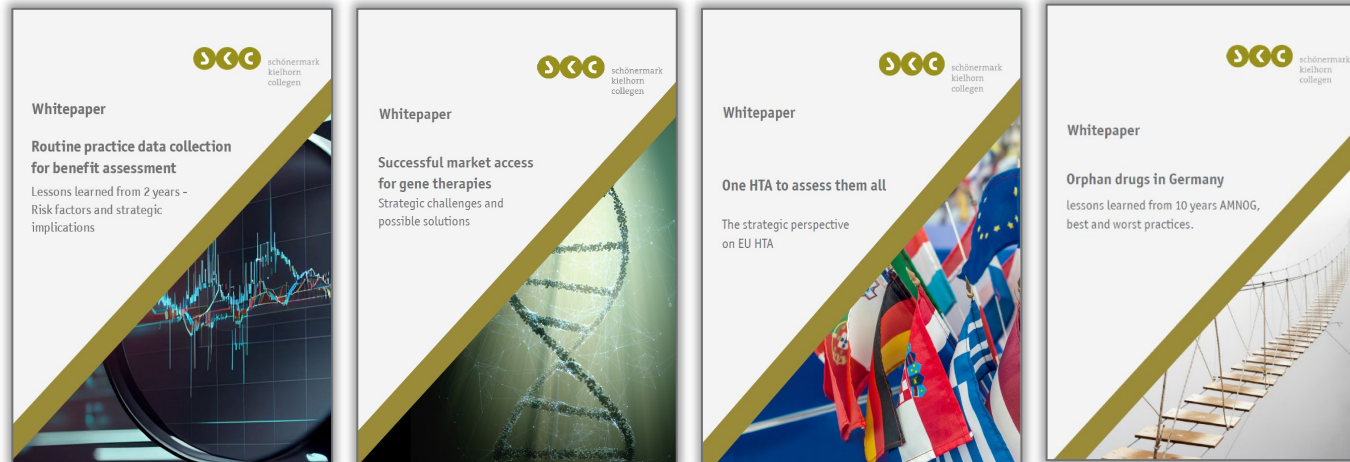
- **50% of all SKC projects** address orphan drugs.
- Since 2016: **50+ different orphan drugs strategically and/or operationally supported** (about ~35 in AMNOG ¹).
- **Proven to be more successful:** \emptyset net discount² with SKC 18.0% (\pm 10.5) vs. 23.3% (\pm 12.5) without SKC.
- Extensive experience involving metabolic and hematologic diseases.



We offer full support, and our clients particularly appreciate our strategic approach.

SKC expertise: orphan drugs

We publish smart analyses and their strategic implications,...



Orphan drugs are a core topic of our publications, such as **white papers**

...also to listen to.

Our (mainly German) **SKC podcast** “The Profcast - rare diseases and their therapies” aims to address the special circumstances of patients with rare diseases, the associated medicine and the challenges for research, development, economics and reimbursement.



@Spotify

We are opinion leaders and lead international discussions.



We are the strategists.

Presentation on “Strategic challenges of orphan drug market access in Europe” at the Harvard Faculty Club.

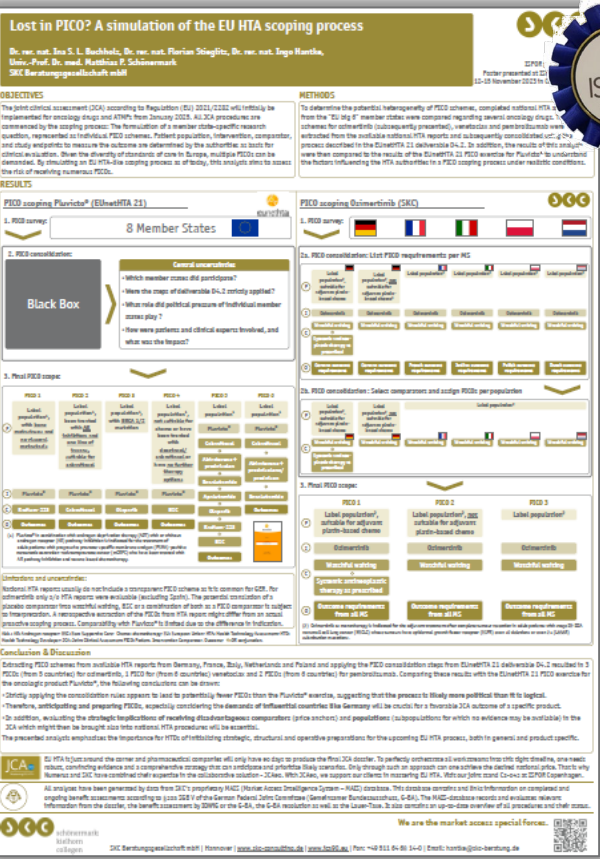


Sources: <https://skc-beratung.de/de/themen/publikationen/index.php>, SKC experience.



How we think about EU HTA is well recognized by industry and authorities.

SKC's EU HTA expertise



- Our **strategic assessment of the planned PICO scoping process** was published at the ISPOR 2023.
- The poster focused on the **complex situation for oncology products** in the PICO black box.
- It earned **Top 5% honors** and was extremely well received among industry and authority representatives.



- In Nov 23 we published our whitepaper on the strategic implications of EU-HTA.
- The **first of its kind publication** provides a concise yet comprehensive overview of **how the industry can navigate the EU-HTA framework**.
- In addition, we were among the most active contributors in the **EUnetHTA guiding process** and have continuously **informed our clients and the public**.

Sources: <https://skc-beratung.de/de/themen/publikationen/index.php>, SKC experience



At European and national level, we support our clients in the strategic and operational preparations for EU HTA.

Our current EU HTA service portfolio - examples

Strategic and operational preparation for EU HTA



Training and individual strategic classification of the process

Organizing educational and encouraging workshops to discuss new requirements and strategic implications



Organisational development

Executing of design thinking workshops to restructure the company and optimize processes



Strategic Sparring & Stress Test

Supporting and / or reviewing of the first Joint Scientific Consultation (JSC) or Joint Clinical Assessment (JCA) submissions, stress testings of the strategy



Full support for the EU HTA process



Joint Clinical Assessment (JCA)

Strategic and operational support during the JCA: from the development of the Value Story, PICO simulations and Gap analysis to the compilation of the submission dossier and factual accuracy check



Joint Scientific Consultation (JSC)

Strategic and operational support in the application for a JSC, strategic and operational support in planning and preparation of the meeting and implementation of the received advice



Transfer of EU HTA results into the German context

Seamless transfer of the EU HTA procedure to the benefit assessment by the G-BA, as well as the strategic and operational preparation of the price negotiations with the GKV-SV. In the best case, we individually co-developed an anticipatory strategy at the beginning as a full support provider.

In principle, the PICO scoping process is clearly defined, yet has caused a high level of uncertainty.

EU HTA: PICO scoping

The formal process



- All 27 MS will be asked to submit their PICO scheme.
- Subsequently, **the individual schemes are pooled and consolidated.**
- The manufacturer has **3 months to compile the dossier** incl. the confirmed consolidated PICOs.



The uncertainties



- The consolidation process is a **black box** (political pressure, pricing pressure, vs. formal approach etc.).
- The **origin of each PICO is not communicated.**
- The **consequences** of not addressing the respective PICO are **not entirely clear.**



Our aim



- It is not about defining the list of all theoretically possible PICOs, **it is about anticipating the final scope for a new product**, and...
- ...in consequence a **realistic anticipation** of if and how the **evidence gaps can be addressed on EU and national level.**



Our approach



- **Understanding the precise indication and typical pitfalls.**
- **Combining expert opinion and desk research, we build a profound hypothesis on the expected final PICO list.**



Despite the remaining uncertainties, one must keep the overall aim in mind: EU HTA is not about addressing all PICOs that are theoretically possible. It is about reaching the desired reimbursed price level and get as many patients as possible on treatment.

JCA90 - a unique blend of Numerus and SKC expertise and skills provides the best-in-class resource for mastering EU-HTA.

What is JCA90?

numerus

Numerus is a boutique statistical consultancy supporting the market access and reimbursement activities of pharmaceutical, diagnostic and medical device companies.

Key expertise:

- Cutting-edge statistical expertise
- More than 20 years of project experience in the European HTA market as well as with German AMNOG
- Innovative methods & technologies for evidence generation
- Frontrunners of statistical science



SKC is a strategic consultancy focused on the increasingly challenging market access environment of innovative drug products. We support both on a strategic and an operational level.

Key expertise:

- Approaching HTA and pricing strategically
- Extensive EU-HTA experience and expertise (EUnHTA 21 Stakeholder/ participation in guideline development)
- Linking EU HTA to national commercial success
- Understanding of organizational changes to prepare for paradigm shifts (AMNOG, EU HTA)



Together we combine robust, convincing evidence with comprehensive strategy to form JCA90 to help our clients master the challenges of EU HTA – most prominently the compilation of a JCA submission dossier within 90 days.

Source: JCA90



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