PRMA Consulting

Pricing, reimbursement, and market access

Capabilities 2014

www.prmaconsulting.com

prmaconsulting®

Innovative and integrated solutions for market access strategy, evidence generation, and value communication

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PRMA Consulting

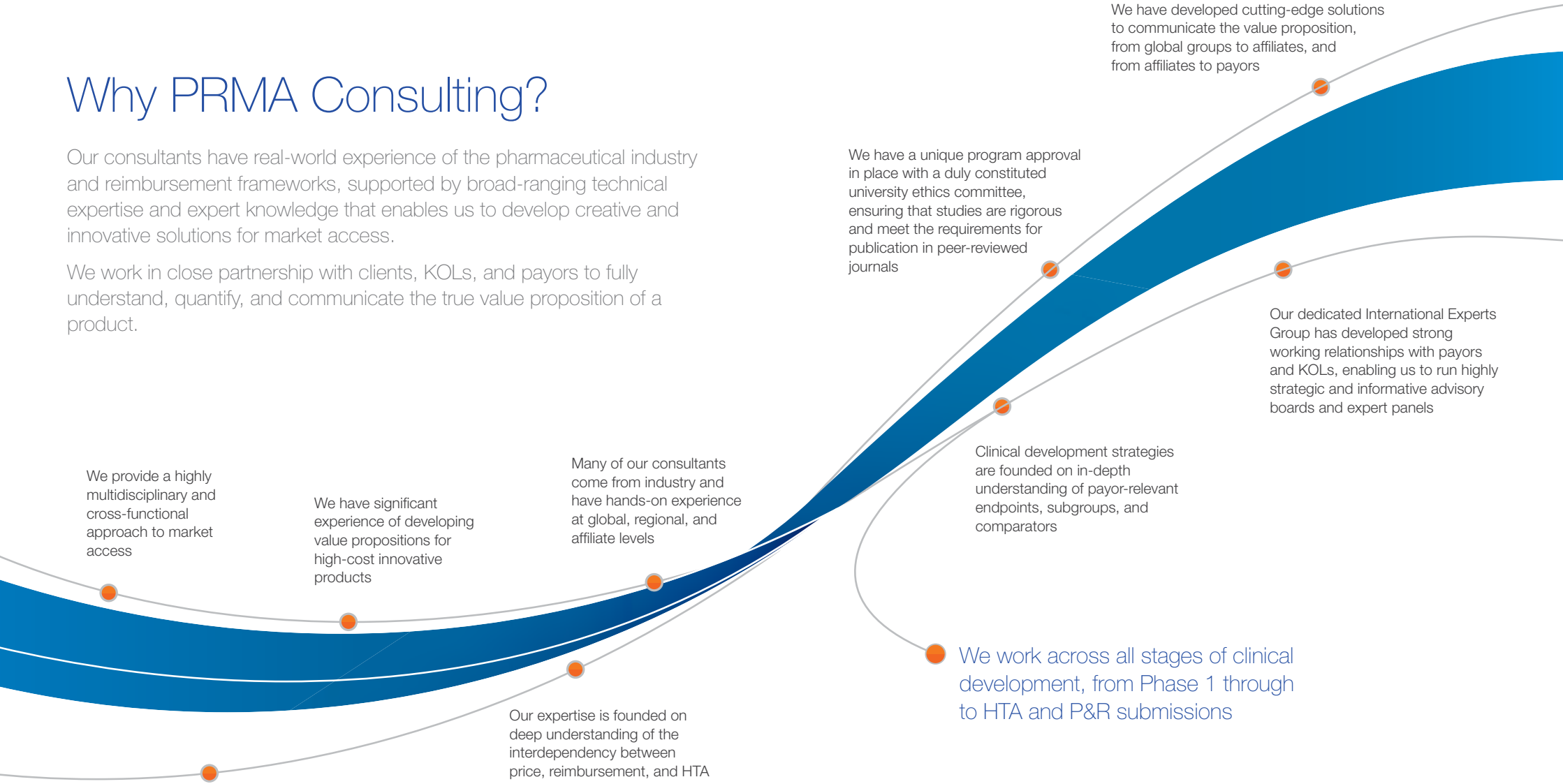
PRMA Consulting are experts in pricing, reimbursement, and market access. We work in close partnership with our clients to deliver integrated and innovative solutions to market access.

- Strategy development – our creative but pragmatic market access strategies are founded on early planning and strategic thinking to understand the challenges.
- Evidence generation – the broad cross-functional expertise and thought leadership of our 75+ strong consultancy team enables us to deliver novel and scientifically rigorous payor-focused evidence generation solutions that meet the needs of both global and affiliate groups.
- Value communication – we develop innovative ways to communicate the value proposition of products to payors and other stakeholders.

Why PRMA Consulting?

Our consultants have real-world experience of the pharmaceutical industry and reimbursement frameworks, supported by broad-ranging technical expertise and expert knowledge that enables us to develop creative and innovative solutions for market access.

We work in close partnership with clients, KOLs, and payors to fully understand, quantify, and communicate the true value proposition of a product.



We provide a highly multidisciplinary and cross-functional approach to market access

We have significant experience of developing value propositions for high-cost innovative products

Many of our consultants come from industry and have hands-on experience at global, regional, and affiliate levels

Our expertise is founded on deep understanding of the interdependency between price, reimbursement, and HTA

We have critical understanding of the challenges of developing market access strategies for early launch based on single-arm Phase 2 data

We have developed cutting-edge solutions to communicate the value proposition, from global groups to affiliates, and from affiliates to payors

We have a unique program approval in place with a duly constituted university ethics committee, ensuring that studies are rigorous and meet the requirements for publication in peer-reviewed journals

Our dedicated International Experts Group has developed strong working relationships with payors and KOLs, enabling us to run highly strategic and informative advisory boards and expert panels

Clinical development strategies are founded on in-depth understanding of payor-relevant endpoints, subgroups, and comparators

We work across all stages of clinical development, from Phase 1 through to HTA and P&R submissions

> PRMA Consulting is the best consultancy we've worked with in every way – flexibility, responsiveness, adherence to timelines, and quality of the work."
>
> Head of Market Access, Health Economics, and Pricing

Our team

David Sykes
Extensive experience in P&R, market access, and health outcomes from senior leadership roles in industry and consultancy; provides strategic insight into the complex issues involved in bringing high-value innovative products to market, in a broad range of therapy areas.

Sotiria Papanicolaou
Broad industry experience in global strategic market access and HEOR; leads some of our most complex, multi-faceted market access projects, developing P&R strategies and evidence generation strategies for products in Phase 2 and 3 trials across a range of therapy areas.

Mark Larkin
Extensive experience in strategy consulting and market access; works closely with emerging biotechs to support in-house commercialization and out-licensing, as well as big pharma clients.

Professor Deborah Saltman AM
Wide-ranging clinical, industry, and consultancy experience; provides critical clinical and industry insight into market access issues; leads the internal Quality Committee.

Annabel Nixon
Extensive consultancy experience in patient-centered outcomes research and implementation, ranging from evidence generation strategies through to development and validation of bespoke instruments.

Jan McKendrick
Extensive industry experience in health outcomes and market access; extensive expertise in semi-quantitative and quantitative research; leads many of our real-world evidence generation activities.

Vanessa Mirsky
Broad consultancy experience in commercialization strategy in healthcare; strong background in managed markets and HTA evaluations and P&R strategy development across global markets.

Casey Quinn
Lead health economist on a range of projects related to economic modeling, evidence synthesis, and HRQoL assessment and measurement; extensive experience in academia and as a former member of a NICE appraisal committee.

Marcus Healey
Extensive experience in evidence synthesis and communication of product value, notably global value dossiers and the development and validation of value messaging.

Clare Jones
Extensive industry experience in R&D and marketing of biotechnology and medical devices, particularly diagnostics and personalized medicine; leads applied research on market access for products with companion diagnostics.

Headquartered in the UK, with offices in Greece and the US

Experience from global, regional, and affiliate P&R and health outcomes roles

Expertise in developing payor-relevant value propositions across a broad range of geographical areas

Complementary scientific, medical, technical, and commercial skill sets, drawing from a variety of backgrounds

Strong cross-functional perspective on market access

Strong expertise in health economic modeling, PROs, evidence synthesis, statistics, and trial design

> I couldn't possibly hope to achieve this level of cross-functional expertise internally"
>
> GHE group lead, top-20 US-based pharma

Integrated solutions that go beyond strategy

Our approach to market access in the current challenging environment is to offer a holistic, integrated solution that extends beyond strategy development to include the generation of payor-relevant evidence and communication of the value proposition in payor-relevant terms.

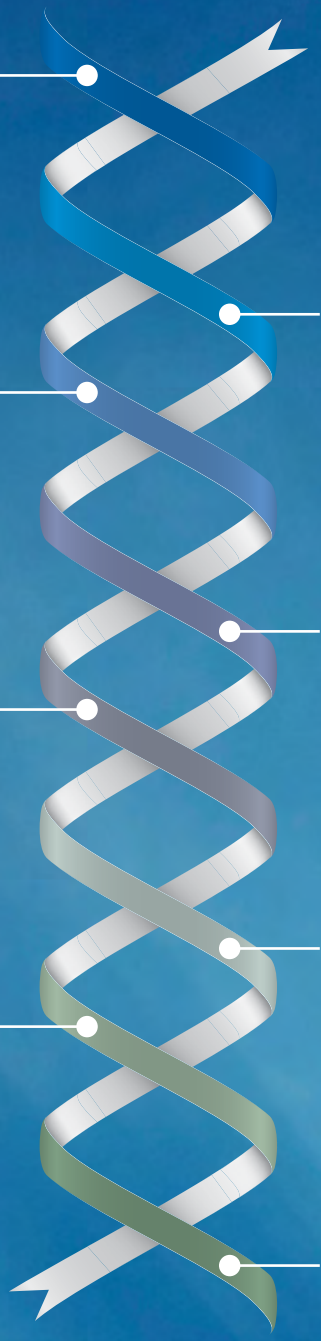
We work in partnership with clients from as early as Phase 1 to develop a value strategy that can evolve as the product moves through clinical development.

We work closely with advisors at all stages to test and refine value strategies through advisory boards and expert panels.

We plan and execute evidence generation activities to support decisions made in trials and models and to define unmet need, to support HTA and reimbursement submissions.

Our global value dossiers are highly strategic and evidence based, mapped to the requirements of HTA agencies in the major markets and thus providing much of the content that affiliates need to develop HTA submissions.

> Your focus on quality and appropriate use of internal experts was particularly strong"
>
> Senior international market access manager, emerging European biotech



Patient-centered outcomes
Strategies to optimize generation of patient-centered outcomes to support the value proposition to regulators, reimbursement agencies, and patients

P&R landscape research
Primary and secondary research to understand the market access landscape and inform strategy with critical analysis of pricing and reimbursement decisions

Evidence synthesis
Focus on comparator landscape assessment and developing networks of evidence to inform indirect treatment comparisons

Personalized medicine
In-depth understanding of the complexities and challenges around market access for companion diagnostic–drug pairings

Real-world evidence
Quantitative research into treatment, disease burden, and resource utilization to inform multiple elements of the market access strategy

Economic models
Cost-effectiveness and budget impact models based on the most demanding HTA agency requirements, underpinned by real-world evidence

Value message testing
Semi-quantitative iterative evaluation, refinement, and validation of value messages with payors and clinicians to maximize the product value proposition

Licensing and acquisitions due diligence
Pricing and reimbursement analyses and strategic recommendations to drive deal terms and lower risk for both in- and out-licensing

Patient-centered outcomes

Data that reflect the patient experience of disease and treatment beyond global HRQoL are becoming increasingly important to inform decision-making by a broad range of stakeholders, from regulators and payors through to clinicians and patients. Patient-centered outcomes data are thus an invaluable element of the value proposition and can support differentiation.

We work with our clients to develop and execute a strategy to generate patient-centered outcomes data that meet the demands of multiple interested stakeholders, as part of the overall value proposition and evidence generation program. This can range from recommendations on endpoint selection and instrument choice through to development and validation of instruments.

- Early identification of relevant endpoints and instruments, which could be patient-reported, clinician-reported, or observed outcomes
- Integration of data collection and analysis into the clinical trial program to maximize efficiency
- Scientifically rigorous methodology that supports publication of data
- Development and validation of instruments to support regulatory labeling

Real-world evidence

Real-world evidence is becoming an increasingly important element of healthcare decision-making as HTA and reimbursement agencies and payors become more demanding in terms of the relevance of clinical evidence and connections to the delivery of care in clinical practice.

Real-world evidence can provide inputs into many elements of the market access strategy, from choice of comparators in pivotal trials to development of economic models.

- Treatment pattern surveys among clinicians provide critical insight and understanding of current drug use, patient selection, treatment decision drivers, and relevant comparators in individual markets.
- Burden of illness studies provide critical insight into the impact of a disease and its treatment on patients and carers, and provide a platform to understand the economic impact of potential changes in treatment.
- Resource utilization studies provide inputs into budget impact estimates and cost-effectiveness analyses that reflect real-world clinical practice.
- Our scientifically rigorous approach to quantitative research is informed by in-depth understanding of payor expectations around real-world evidence.
- We have a unique program approval in place with a duly constituted university ethics committee, ensuring that studies are rigorous and meet the requirements for publication in peer-reviewed journals.

Case study: Treatment pattern survey in oncology

Client

- A major pharmaceutical company developing a new treatment in an oncology indication

Situation

- The recent introduction of new targeted agents had changed the treatment landscape; as a result, the standard of care was not well characterized in the major European markets
- The client wanted to understand how the condition was currently being treated and to investigate clinicians' perceptions of the unmet need in its treatment

PRMA Consulting solution

- A survey questionnaire was developed based on a targeted literature search and in collaboration with leading oncologists
- The web-based survey of 150 clinicians collected information about the treatment of the disease across key countries in Europe
- Data were gathered on which treatments were used and in which patients, the current standard of care, and the guidelines that influenced clinical practice
- The survey also addressed the factors that influence choice of treatment and the potential role of emerging treatments on the standard of care in each country

Client value

- The client was able to identify a range of potential comparators for inclusion in economic models for each core market
- The understanding of current treatment patterns and how these might evolve helped to position their new treatment in context of clinical practice in each country
- A poster of key results was presented at the ASCO 2013 meeting, highlighting the scientific value and credibility of the research

P&R landscape research

In order to understand positioning and pricing, manufacturers need a clear picture of the likely therapeutic and reimbursement landscape into which they will ultimately launch. This insight is critical to inform planning of Phase 3 trials and supporting evidence generation activities and thus needs to be founded on thorough and robust secondary research and informed by payors and clinicians.

Our P&R landscape assessments provide a thorough analysis of the current market and the issues that drive decision-making, thus providing the framework for development of a market access strategy than can evolve through product development and as the landscape changes.

- Assessment of the P&R landscape through critical analysis of existing HTA and reimbursement decisions
- Research to determine willingness to pay based on different endpoint scenarios
- Primary research through advisory boards and interviews with payors and clinicians to understand real-world issues and decision drivers, organized by our dedicated International Experts Group
- Strategic partnerships with clients to further develop and execute the product strategy

Economic models

The development of cost-effectiveness and budget impact models requires a systematic and methodologically rigorous approach, ideally starting early in product development. A thorough and strategic analysis of the evidence base and payor expectations is critical to ensure that clinical trials generate relevant data and that supporting research and evidence generation to inform model inputs is timely and scientifically rigorous. The economic models we develop are an integral part of the overall market access strategy, informed by in-depth cross-functional expertise in pricing and reimbursement and payor-critical issues.

- Models are built to meet the requirements and expectations of the most demanding payors, whilst also being adaptable to other markets.
- We have the technical capability and payor experience to understand and implement appropriate modeling methods (e.g., Markov models, discrete event simulation models).
- We understand the importance of HRQoL and utility data to demonstrate cost-effectiveness in a range of HTA jurisdictions. This includes trial-based analysis, mapping from non-generic instruments, and executing preference elicitation studies.
- We have significant country-level experience, which enables us to collect and analyze multi-country product-specific healthcare resource use and cost data.
- We have executed supplementary statistical analysis of registration trial data, to close evidence gaps to support cost-effectiveness analyses and HTA/ reimbursement submissions worldwide.

Case study: Global payor research to inform go/no-go decision and Phase 3 design

Client

- Top-20 global biopharma company with a product to treat kidney disease in patients with diabetes

Situation

- The client wanted to understand the unmet need in the proposed indication and likely market access and pricing scenarios
- The client also wanted to understand optimal endpoints to support positioning

PRMA Consulting solution

- Secondary research to understand the current and likely future treatment landscape; critical analysis of HTA and reimbursement submissions
- Structured interviews and discussion with 30 payors and 21 KOLs across seven scope countries to understand:
  - relative merits of primary, secondary, and surrogate endpoints, how these are perceived by payors, and how they might be improved by narrowing the patient population
  - key factors that would optimize reimbursement and pricing

Client value

- Detailed analysis of HTA expectations and supporting pricing expectations in each scope country to support rationale for “go” decision to executive leadership
- Recommendations relating to Phase 3 design relating to endpoints, patient populations, and a PRO strategy
- Optimal pricing scenarios assuming additional evidence generation

Evidence synthesis

Regulatory and reimbursement agencies worldwide demand synthesized evidence, principally around clinical efficacy but often also around PROs and costs. In addition, evidence synthesis, systematic review, and indirect and mixed treatment comparisons are typically required for all relevant comparators, not just the product for which approval is sought, and must be conducted according to the methodological requirements for systematic reviews – which vary country by country.

We draw on extensive experience – at the technical and methodological level, and also at the industry and payor level – to execute evidence synthesis projects to support HTA submissions and market access strategy, ranging from evidence review and systematic reviews, to network of evidence, indirect/mixed treatment comparisons, and network meta-analysis.

- We have in-depth understanding of the methodological requirements for systematic reviews to support submissions to all the key national and local agencies.
- Our experience and expertise in evidence generation to support global value dossiers and reimbursement submissions enables us to design and execute integrate projects to support clinical, humanistic, and economic projects, value messages, and reimbursement strategy.
- Our payor experience, coupled with our network of payor advisors worldwide, means that we remain on top of changes to evidentiary requirements and methodological guidance.

Value message testing

Value messages are a critical element of the market access strategy, providing the framework for the value proposition and global value dossier. It is thus imperative that value messages are relevant to and have supporting evidence.

We have developed a cutting-edge iterative process for the evaluation, refinement, and validation of value messages with payors and clinicians.

- Provides semi-quantitative measurement of the relevance, importance, and credibility (RIC) of value messages.
- Progress from conception through to validation of value messages and movement towards or away from consensus is presented using visual representations of the RIC framework.
- Intrinsic to the success of this approach is our extensive network of payors, payor advisors, and clinicians with whom we work regularly, managed by our dedicated International Experts Group.

> This is the best long-term engagement I have ever had”
>
> Head of oncology GHE group, top-20 pharma

Case study: Value messaging to support a GVD for an oncology biologic product

Client

- A medium-sized biotech company with a targeted biologic

Situation

- In light of a label change based on new data, the client wanted to update the value messaging and global value dossier to improve the positioning of their biotherapeutic and reinforce the value of a redefined patient population to payors

PRMA Consulting solution

- Development of value messages in collaboration with the client
- Testing of the value messages with clinicians and payors in the key markets using the RIC framework, through an iterative process involving revising and retesting of concept and wording to reach consensus

Client value

- The semi-quantitative measurement of RIC and evolution of this through iterative testing provided clear insight into issues that resonated most with payors
- The value messages provided the framework for the global value dossier and for development of other materials such as objection handler to support reimbursement submissions

> The GVD is ahead of where it needs to be at this time point – everything was set out for us to choose from”
>
> Oncology global HE team lead, major international biotech

Personalized medicine

The market access environment for drugs paired with companion diagnostics is complex and evolving rapidly. Success requires an integrated strategy for the drug and test to ensure that the requirement for a test does not become a barrier to prescription of the drug. Manufacturers face many challenges in terms of understanding payor expectations for each element of the pairing, how these vary between markets, and thus the evidence generation that is required to support reimbursement.

- We have substantial experience and understanding of the issues and challenges founded on consultancy work and development of ***PRMA Insights:*** *Market Access Success for Companion Diagnostic–Drug Pairings in Oncology.*
- We work closely with clients to evaluate the specific context of each drug–diagnostic pairing and to anticipate trends and developments in order to best prepare for launch and HTA submissions.
- We have conducted extensive primary research with payors to understand how their thinking around reimbursement of co-dependent technologies is developing, the issues that pathologists face in implementing testing, and oncologists' experience of using testing.

Licensing and acquisitions due diligence

Pricing and reimbursement issues are key determinants of the commercial opportunity for an asset and have therefore become a core part of due diligence for licensing and acquisitions deals. We have advised on licensing and acquisitions due diligence for both in-licensors (e.g., large and speciality pharma) and out-licensors (e.g., small and emerging biotechs).

- Analysis of likely reimbursement and treatment landscape into which a product is likely to be launched
- Primary research to understand pricing opportunity and likelihood of reimbursement
- Practical recommendations on the design and execution of clinical trials to maximize the deal offering

> "Very very impressive. The most thorough literature review I've seen – lots of explanations and cross-checks. The workbooks are brilliant – everything you could possibly want. I could pretty much include this in a submission with very little modification. Wow!"
>
> Health Economics Senior Manager, top-20 global pharmaceutical company

Case study: Market access strategy for a companion diagnostic–drug pairing

Client

- Medium-sized biotech developing a targeted oncology product with a companion diagnostic

Situation

- The market access and reimbursement of companion diagnostic tests is unclear and evolving rapidly
- The diagnostic partner is responsible for commercialization of the diagnostic test
- Another drug–test pairing is likely to be launched in the same indication at around the same time

PRMA Consulting solution

- ***PRMA Insights:*** *Market Access Success for Companion Diagnostic–Drug Pairings in Oncology* used to explain the market access environment for co-dependent technologies in key markets
- Primary research with pathologists to understand how the diagnostic would be evaluated and adopted in laboratories, and with payors to understand the likely reimbursement situation for the drug–test pair
- Analysis of the market access environment and potential competitor activities in order to anticipate the likely impact on launch, funding, and uptake of the product and test

Client value

- Development of a market access strategy and evidence generation plan, with prioritization of activities
- Multi-stakeholder discussions to plan coordinated development of the drug and test
- Informed decision-making relating to likely manufacturer funding of the test

PRMA Insights

PRMA Insights are a key resource that provide the basis for planning a market access strategy in a particular therapy area. We have analyzed the current treatment and reimbursement landscapes in detail, and have identified the key issues that need to be addressed in developing the market access strategy.

- Developed by our experienced consultants with in-depth knowledge of all aspects of evidence generation market access, pricing, and reimbursement
- Key practical and actionable strategic insights and recommendations to inform your market access strategy
- Validated by national and international opinion leaders
- Areas to watch: issues that could prevent additional risk to your clinical development program and affect strategy development, and therefore need to be monitored

Learn more about these resources at www.prmaconsulting.com/insights

PRMA Insights: Market Access Success for Companion Diagnostic–Drug Pairings in Oncology

A groundbreaking report that addresses the challenges that manufacturers face in bringing such pairings to market and how these are best addressed throughout the development program to ensure an integrated market access solution for the pairing

PRMA Insights Focus: The Impact of AMNOG on Pricing and Reimbursement in Germany and Beyond

The first in our Focus series, this report provides critical analysis of benefit assessment in Germany: how manufacturers can succeed within this new more stringent framework

PRMA Insights: Pricing and Reimbursement Success in:

- NSCLC
- Metastatic Breat Cancer
- Renal Cell Carcinoma
- Rheumatoid Arthritis
- Type 2 diabetes
- Psoriasis
- COPD

> This is the most insightful assessment of market access issues for companion diagnostics that I have seen"
>
> Diagnostic manufacturer comment to their biotech partner

Join our webinars

We regularly host webinars on issues that we consider to be of critical importance in market access, such as companion diagnostics, benefit assessment in Germany, and the increasingly important role of PROs in oncology.

Meet us face to face

Join us at one of the international conferences that we regularly attend and discuss your market access challenges face to face.

To learn more and to register for forthcoming webinars and events visit **www.prmaconsulting.com/events**

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