Drive readiness for payer submissions for your Phase 2 and 3 products

Recommendations from top-10 pharmaceutical and biotechnology manufacturers who have transformed their strategic market access processes with the PRMA Healthcheck®.

Market access success across global, regional, and affiliate levels requires understanding of and adapting to evolving treatment landscapes and payer requirements. That's why leading pharmaceutical and biotechnology manufacturers are revolutionizing their processes with the PRMA Healthcheck®, a digital application that drives readiness for payer submission for Phase 2 and 3 products.

The following case studies demonstrate how the digital application will:

Enhance insight   Strengthen collaboration   Accelerate Action

Assessing evidence generation strategies for an asset with a novel biomarker in a rapidly evolving landscape

CLIENT SITUATION

To accelerate organizational action for a new biomarker strategy, a top-10 pharmaceutical addressed challenges, re-invigorated clinical community engagement, and bolstered payer discussions using insight from the PRMA Healthcheck®.

PRMA CONSULTING SOLUTION

Vulnerabilities in market access readiness were identified

- A new biomarker was needed to determine treatment eligibility in an established disease area.
- Prevalence and natural history data were lacking for the biomarker-specific population.
- Limited use of the biomarker in clinical practice was a challenge.

Recommended actions to mitigate vulnerabilities

- Collect robust data on the prevalence of biomarkers in this disease area.
- Engage with the clinical community to support validation and communication of the clinical and biological rationale for biomarker-selection, to aid payer discussions.
- Understand issues around implementation of biomarker testing in clinical practice.

Successful outcomes that had a meaningful impact on market access

- Collaboration was enhanced with well-informed discussions of biomarker strategy.
- The project provided sophisticated understanding of the issues for implementation of biomarker testing in clinical practice.
- Stakeholders drove action, proactively developing innovative solutions to gain buy-in from payers.

> " *The PRMA Healthcheck® provided greater visibility of persistent challenges and drove sophisticated understanding of payer requirements.*
>
> *Executive Director, Global HEOR, top-10 pharmaceutical company*

Identifying critical risks for payer decision-making

CLIENT SITUATION

Seeking a deeper understanding of risks with their current data package, a top-5 pharmaceutical organization was better equipped to evaluate evidence generation options using analysis from the PRMA Healthcheck®.

PRMA CONSULTING SOLUTION

Vulnerabilities in market access readiness were identified

- The non-comparative clinical trial program with surrogate endpoints would not be viewed favorably by payers, as competitors had comparative trials with final outcomes data.
- It would be difficult to position the product in earlier lines, where comparator data may be stronger.
- The combination treatment would lead to greater scrutiny of the limited clinical data, making the economic case very difficult to demonstrate.

Recommended actions to mitigate vulnerabilities

- Consider including a Phase 3 trial focusing on payer-relevant endpoints in the clinical development plan, to establish the comparative clinical benefit of the treatment in the specific patient population(s) of interest.
- Consider positioning the treatment as end-of-line, or for specific subgroups of patients (if data are supportive), where payers may be more willing to accept unmet need and lack of alternatives.

Successful outcomes that had a meaningful impact on market access

- Improved understanding of the risks with the current data package led to the inclusion of new Phase 3 study in the ex-US data package.

> " *Speechless! The results from the PRMA Healthcheck® are truly impressive, and exceed our expectations. This consummate piece of work provides a comprehensive analysis for our current position and an elevated vision for our future plan.*
>
> *Global Market Access Partner, top-5 pharmaceutical company*

Critically evaluating pricing and access risks and opportunities for an asset under different clinical development scenarios

CLIENT SITUATION

Redefining their development plan, a top-5 pharmaceutical company obtained valuable insight when using the PRMA Healthcheck® to critically evaluate likely value assessments and pricing opportunities for an asset in different scenarios.

PRMA CONSULTING SOLUTION

Vulnerabilities in market access readiness were identified

- The current clinical evidence package was based on a Phase 2 single-arm trial.
- Well-established comparators existed that were supported by comparative data.
- Payers were not likely to consider the data for the client's asset as clinically meaningful.

Recommended actions to mitigate vulnerabilities

A critical analysis was required of the likely value assessments and pricing opportunities for the following scenarios:

- launch with Phase 2 single-arm trial
- conditional reimbursement approval based on a Phase 2 single-arm trial, anticipating Phase 3 data
- delaying reimbursement submission to include Phase 3 data.

Successful outcomes that had a meaningful impact on market access

- Including a new Phase 3 trial in the evidence package strengthened the market access opportunity.

> " *The PRMA Healthcheck® project confirmed that a Phase 2–Phase 3 approach is necessary. The readouts have been very well-received, and the leadership team has amended planning to account for a Phase 3 trial.*
>
> *Global Market Access and Pricing Director, top-5 pharmaceutical company*

Reviewing and strengthening payer evidence readiness for Phase 2 products

CLIENT SITUATION

A top-5 pharmaceutical company uncovered the need to review and change their approach to economic modeling when using the PRMA Healthcheck® to drive market access readiness for their Phase 2 product.

PRMA CONSULTING SOLUTION

Vulnerabilities in market access readiness were identified

- No precedent existed in previous submissions for a two-state cost-effectiveness model.
- Payers may be unwilling to accept the approach and criticize the potential overestimation of economic value.

Recommended actions to mitigate vulnerabilities

- Informed, collaborative discussions to support the redesign of the model to align with previously published models.
- Consult clinicians and health economists about the analyses of event-free survival and how the data could be incorporated into the model.

Successful outcomes that had a meaningful impact on market access

- The approach to modeling was reviewed and modified.
- Validation of the modeling approach and supporting data analyses is now taking place.

> *As a powerful aid to decision-making, the PRMA Healthcheck® valued by our team, notably for the intuitive heatmap.*
>
> Head of Market Access, top-5 pharmaceutical company

> *An outstanding piece of analysis with astute outputs. I look forward to making good use of it.*
>
> Senior Market Access Manager, top-5 pharmaceutical company

Demonstrating value using a new approach to economic modeling

CLIENT SITUATION

Using the PRMA Healthcheck®, a top-20 pharmaceutical company quickly identified an opportunity to engage with HTA agencies and an expert technical panel in their exploration of potential approaches to cost-effectiveness modeling.

PRMA CONSULTING SOLUTION

Vulnerabilities in market access readiness were identified

- The accepted approach to modeling maps two secondary endpoints to utilities via an established algorithm, and is treatment agnostic. The client intended to incorporate the potential benefits of the product into the model via a new mapping algorithm. This was likely to receive significant challenge, in particular by NICE and SMC.
- The model could not show credible cost-effectiveness versus relevant comparators in subpopulations.
- Reimbursement was likely to be for a restricted population or late in the treatment pathway.

Recommended actions to mitigate vulnerabilities

- Develop an early model to highlight the key value drivers and the need to collect additional data.
- Hold an advisory board meeting to provide technical input and validate the economic model, including validating an alternative approach to mapping dependent on treatment.
- Hold further country-specific advisory board meetings to validate the clinical assumptions made in the economic model.
- Consult EUnetHTA on the acceptability of clinical endpoints.

Successful outcomes that had a meaningful impact on market access

- Consultation with EUnetHTA is being sought to provided an opportunity to discuss the study design and approach to cost-effectiveness modeling.
- An expert technical panel has been engaged to give insight into the potential approaches to cost-effectiveness modeling.

> "The PRMA Healthcheck® allowed us to capture a comprehensive analysis of the overall landscape beyond the scope of what we would typically undertake internally, in a convenient platform for dissemination.
>
> *Director, Global HEOR, top-20 pharmaceutical company*

Get started

To date, over 40 assessments have been conducted using the PRMA Healthcheck® for top-10 pharmaceutical and biotechnology companies.

Drive readiness for payer submissions for your Phase 2 and 3 products

The PRMA Healthcheck® is a digital application that uses actual payer templates to evaluate commercial and access risks and opportunities. It streamlines processes and aligns global and local market perspectives.

See what top-10 pharmaceutical and biotechnology companies are saying about the PRMA Healthcheck®: prmaconsulting.com/prmahealthcheck

Fully supported

As a global specialist in market access with proven digital skills and resource, we have real-world experience of the global and affiliate perspectives. We help you build a plan for change. This communicates the gap between where you are now and the vision of where you want to be. You are supported from initial adoption and training, through to ongoing user experience and future development.

Complete piece of mind

Our global commitment to excellence protects your reputation. Company-wide, we are committed to providing an exceptional and consistent service to all our clients. With our ISO27001 certification you can be assured that your data are secure, so you can focus on carrying out business as usual.

For a confidential conversation about using the PRMA Healthcheck® to address your market access challenges, just get in touch.

→ **Request a demonstration**