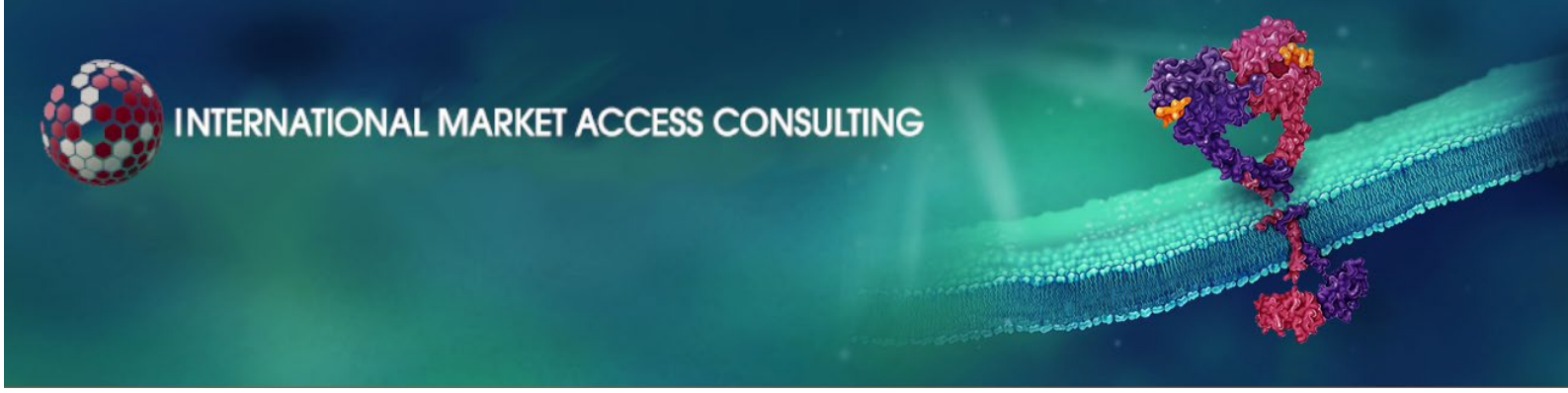


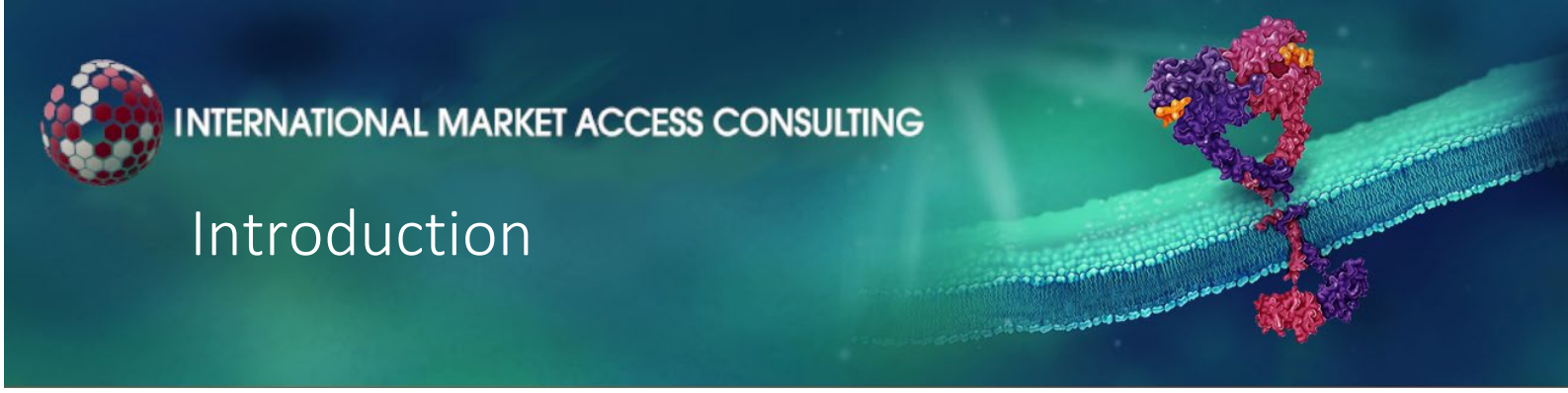
INTERNATIONAL MARKET ACCESS CONSULTING

Where expertise drives strategy

Reimbursement Submission: Achieving Premium Pricing and Reimbursement in a Saturated Market

imarketaccess.com
imac@imarketaccess.com
European Office:
+44 7748 742 540
North American:
+1 514 294 4016

Introduction



International Market Access Consulting (IMAC) was mandated to provide strategic advice and develop the reimbursement submissions for a product facing several challenges and barriers to reimbursement in Canada. The product was planned to be introduced into a highly saturated and genericized market. In addition, the Common Drug Review (CDR) and "Institut National d'Excellence en Santé et en Services Sociaux" (INESSS) had previously recommended against the reimbursement of the product.

OUTCOME OF THE PROJECT

Reimbursement, at a premium price, was obtained for all submissions in record time.

IMAC completed reimbursement submissions for 11 provinces and patient groups, including INESSS in Québec. All the submissions were successful, and resulted in the reimbursement of the product at a premium price, despite the existence of cheaper alternatives already in use.

The project included the following tasks:

1. IMAC defined the value story by building a narrative and the appropriate economic model to justify the premium price for the drug in a field of less expensive alternatives.

2. IMAC conducted an exhaustive literature search and a comprehensive review of the current treatment and unmet needs. Based on this research, IMAC wrote the clinical and executive summary for the INESSS submission.

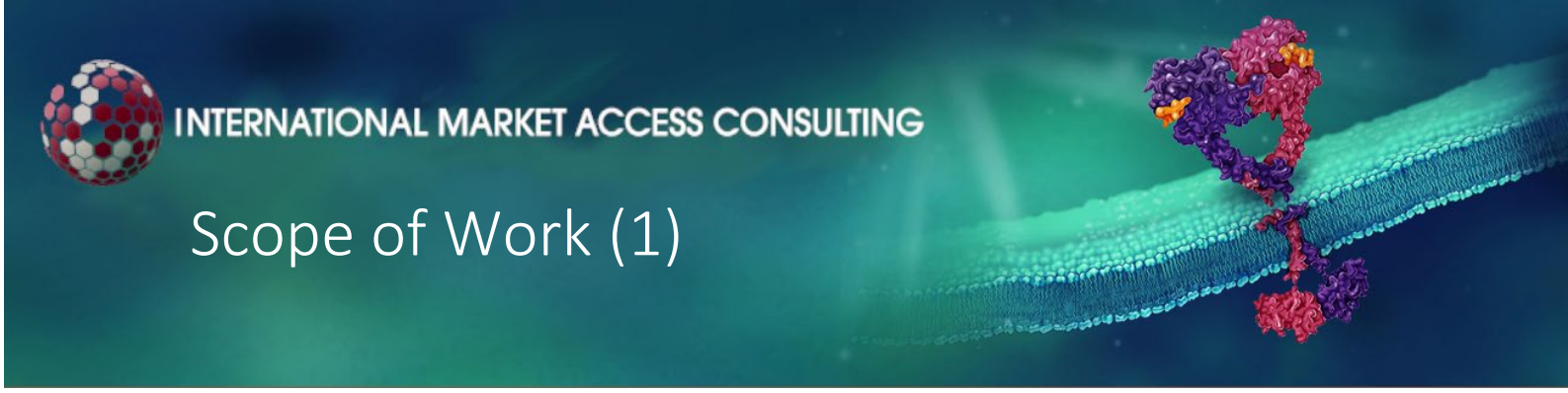
3. IMAC built the economic model for the product and produced a technical report for the province of Quebec (INESSS). IMAC adapted the economic model to British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and the Atlantic Common Drug Review (ACDR) for the CDR submission.

4. IMAC created a core budget impact analysis (BIA), and produced a technical report, for the province of Quebec (INESSS). IMAC adapted the BIA for the other 10 provinces/programs (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Newfoundland, Prince Edward Island, and the Non-Insured Health Benefits [NIHB] program) across Canada.

5. IMAC completed the "Information sur les effets sur la santé" and the "Justification du prix" forms for the INESSS submission.

6. IMAC prepared the submission for INESSS, including the translation and adaptation of the executive summary, the clinical summary, and the technical reports for the BIA and the CE model. IMAC prepared the reimbursement submissions for British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and ACDR.

Scope of Work (1)



DEFINE THE VALUE STORY TO PRESENT IN THE SUBMISSIONS

In collaboration with the client, IMAC identified the positioning and key messages to build the value story presented in the submissions.

REVIEW OF THE LITERATURE AND RELEVANT DOCUMENTS

IMAC reviewed all published and unpublished documents and assessed the quality of the available data. The most appropriate literature was identified to support the key value messages presented in the reimbursement dossiers.

BUILDING THE ECONOMIC MODEL

IMAC conducted comprehensive literature searches and reviews that identified the existing economic evaluations available for the therapy and its comparators.

IMAC, in collaboration with the client, determined the most appropriate approach to adopt for developing the economic model.

Study Question

A clear study question was addressed by the evaluation and defined in an answerable form.

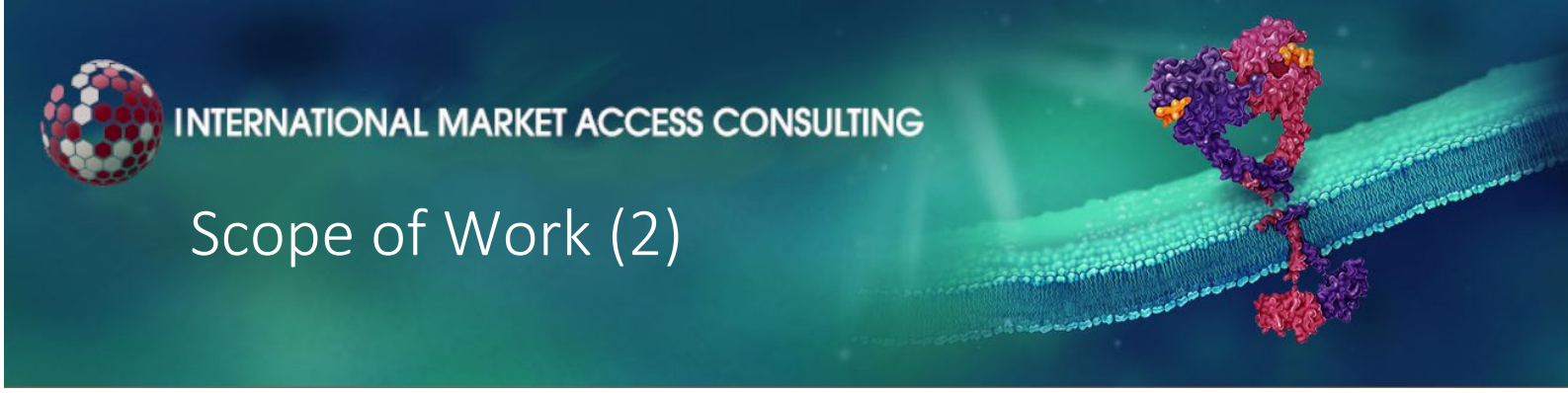
Target Population

The defined target population captured all of the product's expected use. The analysis was performed for the entire target population specified by the study question. The efficacy-effectiveness data selected for the economic model were relevant to the target population in the analysis.

Comparators

The choice of comparators were related to the study population and current Canadian practice. All technically feasible, acceptable, and relevant alternatives were considered as potential comparators. IMAC described and justified the comparators that were chosen for evaluation.

Scope of Work (2)



Perspective

The perspective of the publicly funded healthcare system was used for the base case scenario. The costs associated with adopting a wider perspective were reported separately along with an assessment of their impact on the results of the analysis.

Time Horizon

The time horizon for the economic model was based on the natural course of the condition and the likely impact that the intervention had on the disease.

Costing of resources

All resources relevant to the study perspective(s) were identified and valued for the province of Quebec. The cost of the comparators were adjusted for the following submissions: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and ACDR.

Uncertainty

A deterministic sensitivity analysis was conducted systematically and thoroughly, and the impact on the results and conclusions were described.

Model Validation

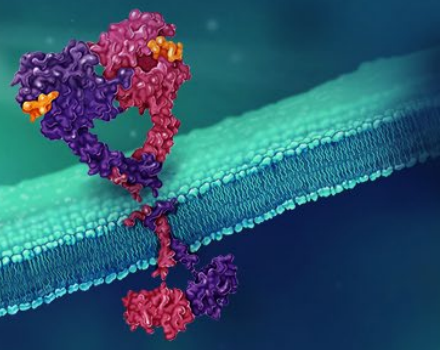
The structure of the economic model and assumptions were validated with key opinion leaders (KOLs).

Quality Assurance

The economic model was audited for quality assurance. An IMAC pharmacoeconomic expert who had not built the model checked all formulae and data entered in the model to ensure their internal validity.

imarketaccess.com
imac@imarketaccess.com
European Office:
+44 7748 742 540
North American:
+1 514 294 4016

Scope of Work (3)



Technical Report

A comprehensive report was written in a transparent and detailed manner, based on the reporting structure suggested in the Guidelines for the Economic Evaluation of Health Technologies: Canada. Adequate information was provided to enable the audience to critically evaluate the validity of the analysis. The report also included a list of all the assumptions that were required to build the model and a discussion section which described the main findings, the strengths, and the weaknesses of the study.

DEVELOPMENT OF THE BUDGET IMPACT ANALYSES FOR THE DRUG PLAN PROGRAMS IN CANADA

Based on the value story and positioning of the therapy, IMAC built the core BIA for the province of Québec, which was subsequently adapted to the other 9 provincial drug programs and the NIHB program in Canada.

Model Design

At the request of the client, IMAC designed the BIA in Microsoft Excel®. The BIA and supporting report were designed in a transparent and accessible manner using the simplest possible design structure to answer the budget impact question. The technical report explicitly described all choices and assumptions.

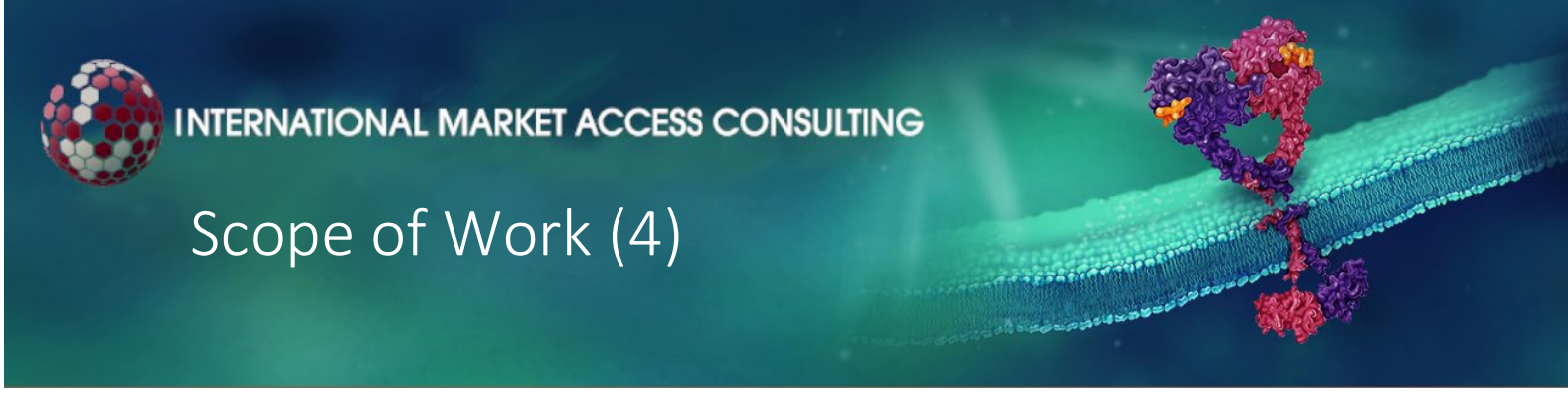
Perspective and Scenarios to be compared

The BIA was performed from a payer perspective and included drug-related costs. Two scenarios, one for the Reference Scenario (the market without the therapy) and one for the New Drug Scenario (the market with the therapy), were compared. All assumptions made to develop each scenario were explicitly described and justified using the best available information, such as historical data from other markets, published forecasts, or when necessary, validated by a KOL.

Population

The target population was defined based on the client's product monograph, plan eligibility, and any restrictions to drug access intended by the client. Growth of the market over time was based on general population growth estimates, with suitable adjustments made when the drug availability was anticipated to affect the size of the market. Four years of data were presented including a one-year baseline period and a three-year forecast period. All forecasted data and results were presented for 12-month periods relative to the intended date of formulary listing.

Scope of Work (4)



Relevant Comparators

The comparators reflected drug-based treatment strategies used to treat the same indication as the therapy. Non-drug treatments were excluded from the treatment strategies used in budget impact calculations.

Drug Prices

To price each treatment strategy, IMAC obtained reimbursement prices from the best available source(s), including, but not limited to: the drug plan formulary, the manufacturer, wholesaler catalogues, and providers of Canadian public drug plan data.

Quality Assurance

The BIA was audited for quality assurance. An IMAC pharmacoeconomic expert who had not built the model checked all formulae and data entered in the model to ensure their internal validity.

Technical Report

A comprehensive report was written in a transparent and detailed manner based on the reporting structure suggested in the Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada. Information was provided to enable the audience to critically evaluate the validity of the analysis. The report also included a list of all the assumptions required to build the model and a discussion section which described the main findings, the strengths, and the weaknesses of the study.

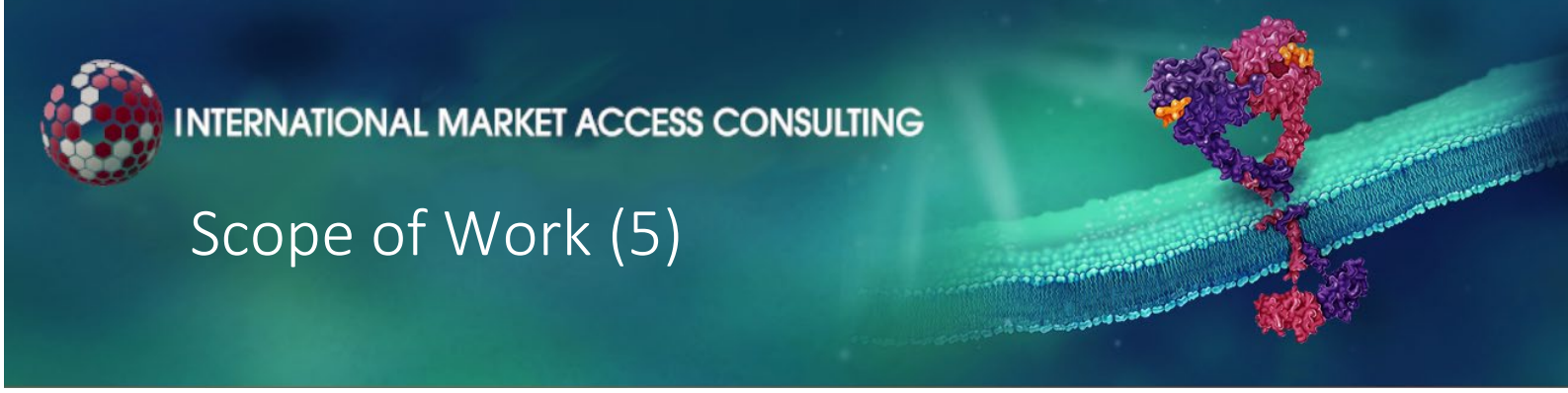
DEVELOPMENT OF THE EXECUTIVE SUMMARY

IMAC wrote a high-level summary of the submission, including a brief description of the product and its place in therapy, a summary of the clinical and pharmacoeconomic evidence (including the unit cost), requested listing criteria, and the rationale.

DEVELOPMENT OF THE CLINICAL SUMMARY

A clinical summary was included in the reimbursement submissions in order to present the value story of the product. This summary included an overview of the disease; the burden of illness; the management strategies as well as the unmet medical needs, and a presentation of the drug including clinical efficacy and safety data from the pivotal clinical trials.

Scope of Work (5)



DEVELOPMENT OF THE « INFORMATION SUR LES EFFETS SUR LA SANTÉ » FORM FOR THE INESSS SUBMISSION

The required INESSS form, “Information sur les effets sur la santé” included epidemiological data on the health condition covered by the drug. Relevant information also included the following concepts: the burden of disease, duration and course of disease or health condition targeted, duration of therapy, the clinical course following the use the drug, the actions needed to monitor the health condition, the continuity in the product's use or control of its adverse effects, and the organizational implications on current health care services.

DEVELOPMENT OF THE « JUSTIFICATION DU PRIX » FORM FOR THE INESSS SUBMISSION

IMAC developed an argument justifying the manufacturer’s list price for the drug, including an analysis of comparators’ prices. The price justification evaluated the differential cost of the new treatment compared to the costs of other treatment strategies (including non-pharmaceutical treatment) with the same therapeutic purpose.

BACKGROUND

The antibiotic product is a synthetic, broad spectrum, bactericidal antibiotic for oral administration. It is available as a single-dose sachet indicated in the treatment of urinary tract infections. The product has broad antibacterial activity against Gram-positive pathogens, with useful activity against *E. faecalis*, *E. coli*, and various Gram-negative bacteria like *Citrobacter* and *Proteus*. Given a greater activity in a low pH milieu, and predominant excretion in active form into the urine, the product is used for the prophylaxis and treatment of uncomplicated urinary tract infections caused by these uropathogens.

INTERNATIONAL MARKET ACCESS CONSULTING

Related Experience

IMAC has considerable experience developing economic models for products across a wide range of therapeutic areas. IMAC has supported strategic global submissions for products in Europe and North America including developing and adapting cost-effectiveness and budget impact models for the UK, Canada, and select European markets.

Additionally, IMAC has considerable experience developing health-technology submissions in the UK, Europe, South America, and North America. IMAC has successfully developed submissions to the National Institute for Health and Care Excellence (NICE) for products in many therapeutic areas. Recently, IMAC developed a successful Highly Specialised Technology (HST) submission for an innovative gene therapy for an ultra-rare disease and Single Technology Appraisal (STA) submissions for a first-line oncology product and a first-in-class monoclonal antibody.

"We've been running on repeat business for the last 12 years. We know how to really build a strong story that links both clinical & economic aspects of your therapy together"
– Louise Perrault, President & CEO

"IMAC consists of a team of people that are experienced in not only developing submissions, but also in rescuing submissions that are struggling for different reasons. We are able to quickly assess the challenge(s), strategize a plan for optimising the value proposition of a product and continue our support throughout the submission process. Because we are a team of experts, we are able to work quickly under tight deadlines that are often challenging for larger firms. We produce the highest quality products, on time and on budget, and we have an excellent success rate."
– Nicole Tunstall, Senior Consultant, HTA and Medical

"We are people with experience, when we speak with our clients, we understand what you're talking about. We know how to develop products that stand up to review because of our expertise."
– Veronique Lauzon, Senior Health Economist

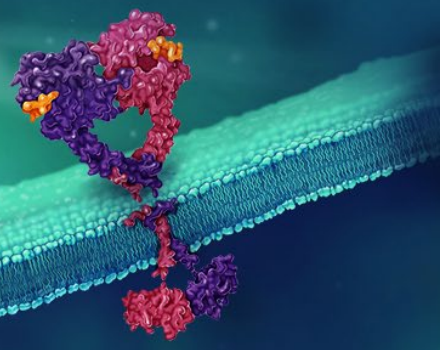
"IMAC is made up of more experienced qualified consultants who understand how to deal with the challenges many companies face when seeking market access for a new therapy. Because of this everything is completed on time, to a high level of quality, and a very good success rate."
– Eva Tsakonas, Senior Epidemiologist, Health Economist

"IMAC is above all a company of experts who are concerned about quality service throughout the duration of your project. We are a team of competent professionals who listen to and care about your needs and will successfully see your products through various evaluation processes while respecting the deadlines imposed."
– Ange Christelle Iliza, Research Assistant

"Working with IMAC is like adding a team of experts to your company for the duration of the project. From the project initiation to the final follow-up, you deal with the same experienced consultants who are there to advise and optimize the project whether it be an economic model, systematic literature review, HTA submission, global value dossier, manuscript, or conference presentation."
– Sarah-Gabrielle Béland, Senior Pharmacoepidemiologist

INTERNATIONAL MARKET ACCESS CONSULTING

Expertise and Achievements



imarketaccess.com
imac@imarketaccess.com
European Office:
+44 7748 742 540
North American:
+1 514 294 4016