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White Paper

Satisfaction With Treatment

The value of capturing the patient's perspective

ANA MARIA RODRIGUEZ, PHD, MSc, PT
ERIC GEMMEN, MA
ALEXANDRA PALMER MINTON, MA
**LOUISE PARMENTER**, MSC, PHD

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Satisfaction with treatment – the value of capturing the patient perspective

A foundational component of patient centricity is gathering feedback from patients on their experience and satisfaction with treatment. Although pharmaceutical manufacturers were once reluctant to use Clinical Outcome Assessments (COA) such as Patient Reported Outcomes (PRO), it is now recognized that regulators and payers expect the use of reliable and valid Patient Experience Data (PED) in drug development. Patient treatment satisfaction is one measure of patient experience that has been frequently used in this context because of its demonstrated ability to improve health outcomes through greater medication adherence.

The Food and Drug Administration (FDA), European Medicines Agency (EMA), and select Health Technology Assessment (HTA) bodies have published guidelines that recommend using COAs that are psychometrically assessed, reflect the patient experience, and are fit for purpose for a given study´s objectives and context.[1-4] Numerous disease-specific measures of patients' treatment satisfaction with medication have been cited in literature, but there are not as many generic measures that apply to treatments or contexts of use. One such generic measure is the Treatment Satisfaction Questionnaire for Medication (TSQM), which has been cited in over 375 publications. This article highlights the importance of measuring treatment satisfaction, as the concept relates to the patient experience and may also relate to improving health outcomes such as medication adherence.
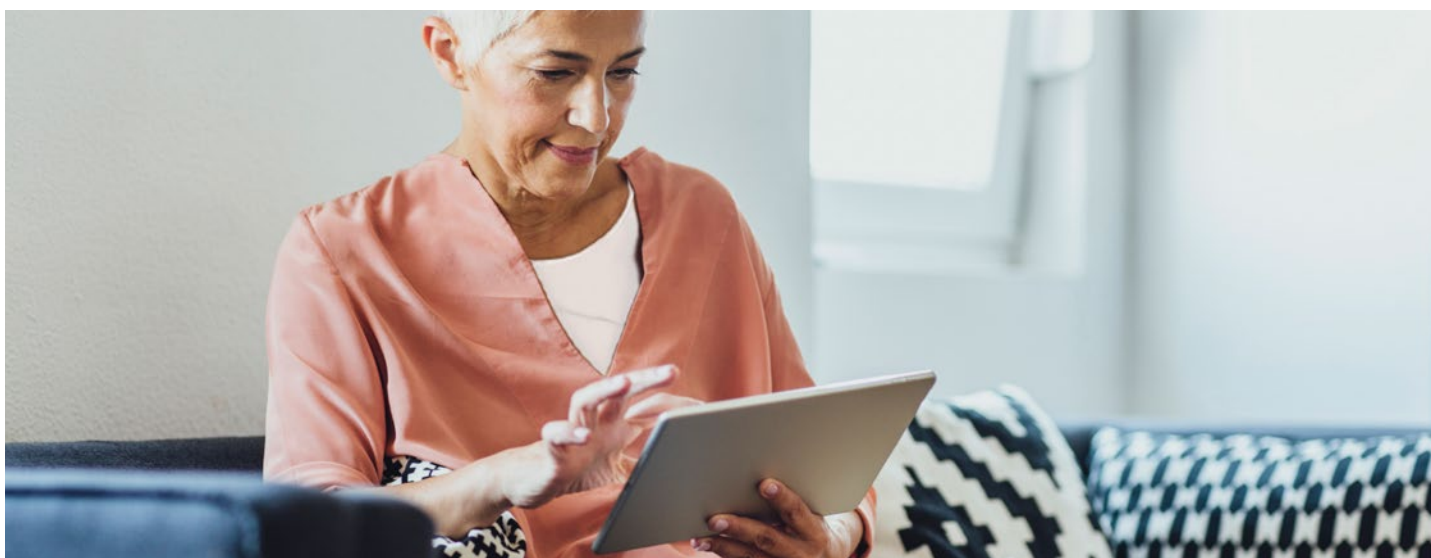
Understanding treatment satisfaction offers a pathway towards effective treatment

Measuring patients' treatment satisfaction has grown in importance over the past three decades,[5-8] as doing so can help to differentiate between alternative treatments. As an endpoint, patient-reported treatment satisfaction is a meaningful, valid, and reliable patient experience measure that is of value to patients, clinicians, industry, academia, and healthcare legislators.
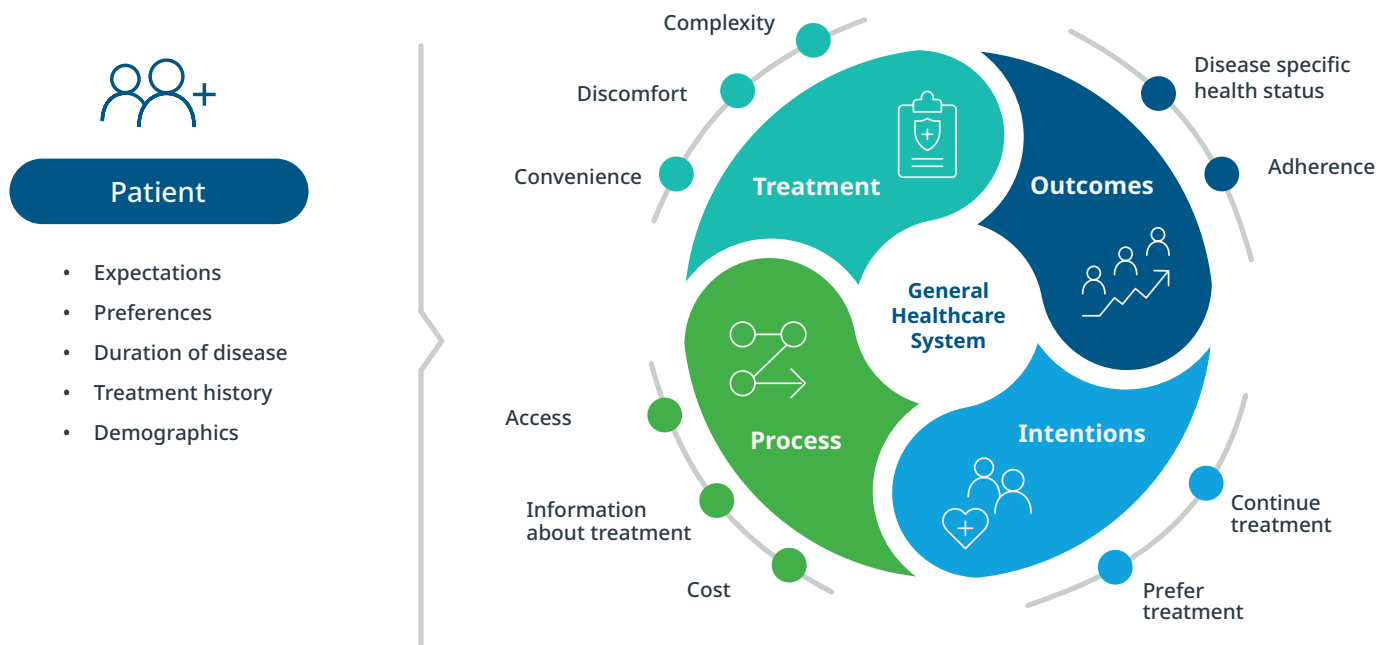
Measures of treatment effectiveness and safety relied on clinical, laboratory and survival endpoints prior to the development of treatment satisfaction-specific PRO instruments. However, patient input is central to assessing the value of treatments. Studies show that factors such as side effects, cost of treatment, drug regimen complexity, disease and treatment comprehension, patient beliefs, expectations and preferences, patient-physician communication, patient-level variables such as previously held expectations, race/ethnicity, demographics, education and other factors influence treatment satisfaction.[6,7,9]

Weaver, et. al. categorized the factors influencing treatment satisfaction into patient- and treatment-related characteristics, ranging from treatment-related effectiveness, discomfort, cost, and regimen convenience (See Figure 1). They reported the domains most often included in treatment satisfaction measures were overall satisfaction (47%), outcomes of treatment (47%), disease-related information (37%), treatment-related discomfort (31%), product design or appearance (31%) and convenience (31%).[10]

Most models used to describe patients' satisfaction with medical treatment conceptualize the patients' decisions to continue, alter or discontinue medical treatment, and include the influence of a variety of characteristics, such as:

» The desire to participate in treatment-related decision-making

» The evaluation of actual and preferred health state

» Prior experiences with particular treatment choices

» Real or anticipated beliefs regarding the effectiveness or harms of treatment

Figure 1: Factors Influencing Treatment Satisfaction[6]

Patient
- Expectations
- Preferences
- Duration of disease
- Treatment history
- Demographics

Complexity
Discomfort
Convenience

Treatment

Disease specific health status
Adherence

Outcomes

General Healthcare System

Access
Information about treatment
Cost

Process

Intentions

Continue treatment
Prefer treatment

Another model, the Decisional Balance Model of Treatment Satisfaction, predicts overall satisfaction and medication persistence, and includes concepts such as the experience of treatment effectiveness, the experience of side effects, and the difficulty or inconvenience of use, which balance and support the decision of the patient to continue or change their treatment (Figure 2).

THE TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION (TSQM) IS A RELIABLE TOOL FOR CAPTURING PATIENT-REPORTED TREATMENT SATISFACTION DATA

Disease-specific evaluations of patients' satisfaction with medication[11-16] have been validated and used, accounting for the conceptualization of the patient experience of treatment satisfaction. An early example of such a disease-specific treatment satisfaction instrument is the Diabetes Treatment Satisfaction Questionnaire,[17] which was first developed in the early 1980s. It is now widely used, particularly in clinical trials, but also for routine clinical monitoring. It is available in more than 100 languages.

Generic measures that allow comparisons across medication types and patients' conditions are rarer. The Treatment Satisfaction Questionnaire for Medication (TSQM) was developed as a generic measure that allows for comparisons between treatments and across diseases. The psychometric properties of the TSQM have been examined, and these studies suggest that the TSQM is a conceptually and psychometrically valid and reliable PRO instrument to evaluate patients' treatment satisfaction with a wide variety of medications.[18]

The TSQM has evolved over time into three distinct versions that can be used to assess the patient perspective on treatment experience and its related satisfaction. Version 1.4 was designed as a general measure of satisfaction with medication, including three most commonly identified dimensions to evaluate patients' medication: medication effectiveness, side effects of use and convenience of use. Preliminary evidence showed that an overall satisfaction rating might be the most predictive indicator of patient satisfaction and adherence.[18]

Figure 2: The Decisional Balance Model of Treatment Satisfaction[15]

Experience of treatment effectiveness

Experience of side effects

Difficulty or inconvenience of use
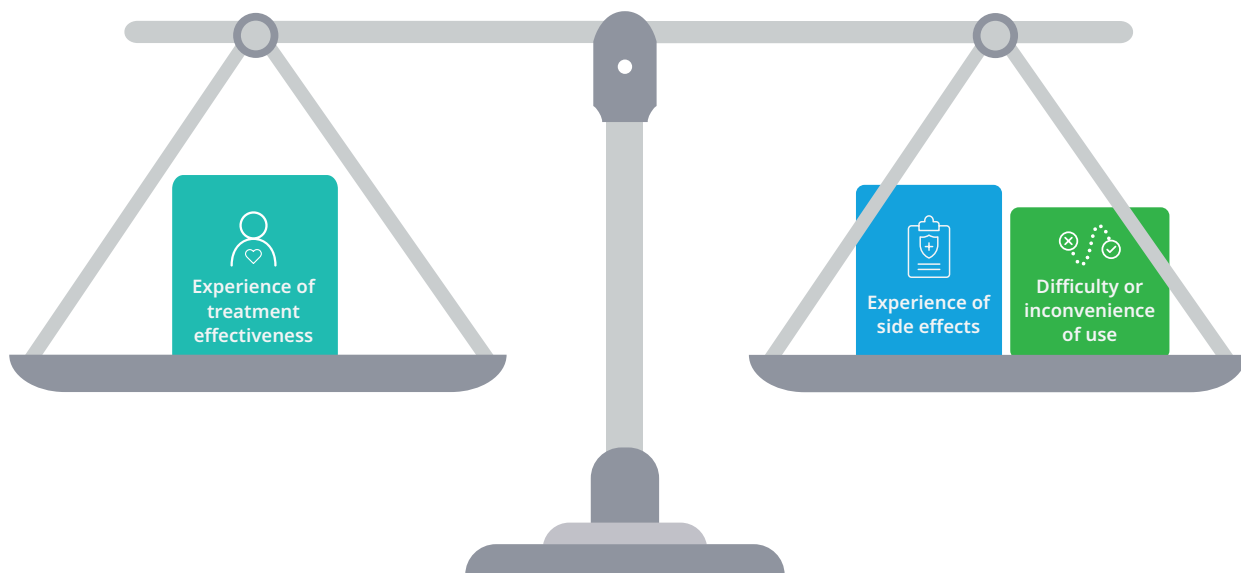
Satisfaction balance influences the patient's decision to continue or change

As a result, the TSQM Version 1.4 consists of 14 questions and covers four domains: Effectiveness, Convenience, Side Effects, and Global Satisfaction.

Based on feedback from subsequent focus groups, three items were removed from Version 1.4 and several items were reworded, resulting in Version II, which consists of 11 items and the same domains as Version 1.4. The TSQM Version II was tested for model fit against an established theoretical model (the Decisional Balance Model of Treatment Satisfaction) using Hierarchical Confirmatory Factor Analysis.

Patient perception of medication side effects is an important predictor of treatment satisfaction based on the conceptual framework of patients' treatment satisfaction with medication. However, in naturalistic studies, administering the TSQM with the side effects domain could provoke the physician to assess the adverse events in a way that is not routine clinical practice.[19] TSQM Version 9 was, thus, developed to provide a reliable and valid measurement that can be adapted in naturalistic study designs to assess treatment satisfaction.[20] Consequently, Version 9 excludes the Side Effects domain and is composed of nine questions and three domains: Effectiveness, Convenience, and Global Satisfaction.

TSQM RESULTS SUPPORT MEDICAL PRODUCT LABELING CLAIMS APPROVALS AND HTA DECISION-MAKING

The TSQM is used to support claims in medical product labeling and for assessing the patient value of pharmaceutical interventions. The European Union and U.S. guidelines recommend ensuring a questionnaire is fit for purpose for a new disease setting prior to applying the instrument to that context. Likewise, in the agency's roadmap for patient-focused outcome measurement in clinical trials, the U.S. FDA advises considering COAs, including PROs, in their context of use.

The FDA provides a comprehensive definition of Patient Experience Data (PED) with acknowledgement of the importance of generating reliable and valid data, ensuring interpretable outcomes, and comprehensively understanding both benefits (efficacy) and risks/harms (safety) to inform decision-making. Treatment satisfaction as experienced by patients, therefore, aligns with the FDA´s definition of PED, that is defined as "information that captures patients' experiences, perspectives, needs, and priorities related, but not limited to: Symptoms of their condition and natural history, the impact of the conditions on functioning and quality of life, the experiences with treatment, the input from patients on which outcomes are important to them, patient preferences for outcomes and treatments, and the relative importance of any issue as defined by patients". The EMA's 'Regulatory Science Strategy to 2025' indicates that Europe is thinking the same way as evidenced in the proposed expansion of its core recommendation for "Ensuring the patient voice is systematically incorporated throughout drug development & associated evidence generation".[21]

To support payer-decision making, studies should include high-quality and transparent evidence from PRO measures that are psychometrically validated in targeted populations

Payers have increasingly been using patient experience data to influence their decision making and it is expected that this type of data will be increasingly influential.[22] The patient voice is being incorporated into HTA decision-making through patient representation, as a number of HTA organizations have developed processes to engage patients in the assessment of new health technologies such as pharmaceuticals, diagnostic tests, devices or medical procedures. It is recognized that patient involvement should take place across the entire HTA process.

The patients´ perspectives on treatment satisfaction can represent the evidence surrounding the added value of the medicine for the patient, including impact on quality of life, symptoms, and convenience of the treatment.

**TSQM OUTCOMES ARE STRONG INDICATORS OF TREATMENT ADHERENCE**

Patient-experienced treatment satisfaction, as measured by the TSQM, may be linked to health behaviors such as adhering to treatments and to clinical recommendations. Measuring treatment satisfaction in clinical practice is thus very valuable to understanding the overall patient healthcare experience. Treatment satisfaction is one component of the overall satisfaction with medical care[23] which includes factors such as timely access to medical staff, quality of medical facilities and the patient's own personal experience with respect to the duration and severity of the disease.

The relationship between satisfaction and adherence

measures of patients' treatment satisfaction have been widely used to evaluate the effectiveness of medical treatments.[24-27] Studies have demonstrated that patients' satisfaction with their medication affects their treatment-related behaviors, such as their willingness to continue to use the medication and their adherence with medication, hence impacting the success of treatment outcomes (see Figure 3).[28-29] Poor adherence to treatment is a major issue for the management of chronic conditions and is also associated with increased healthcare costs.[30-32]

Treatment satisfaction questionnaires are valuable tools for measuring adherence and other endpoints important to key healthcare stakeholders. Studies of patients with hypertension conducted via validated questionnaires have suggested that better blood pressure control and higher treatment satisfaction were both associated with higher adherence.[33, 21]

Figure 3: Connection Between Treatment Satisfaction And Health Outcomes

Appropriate treatment use and treatment success

Health outcomes

Treatment behavior and adherence

Treatment satisfaction
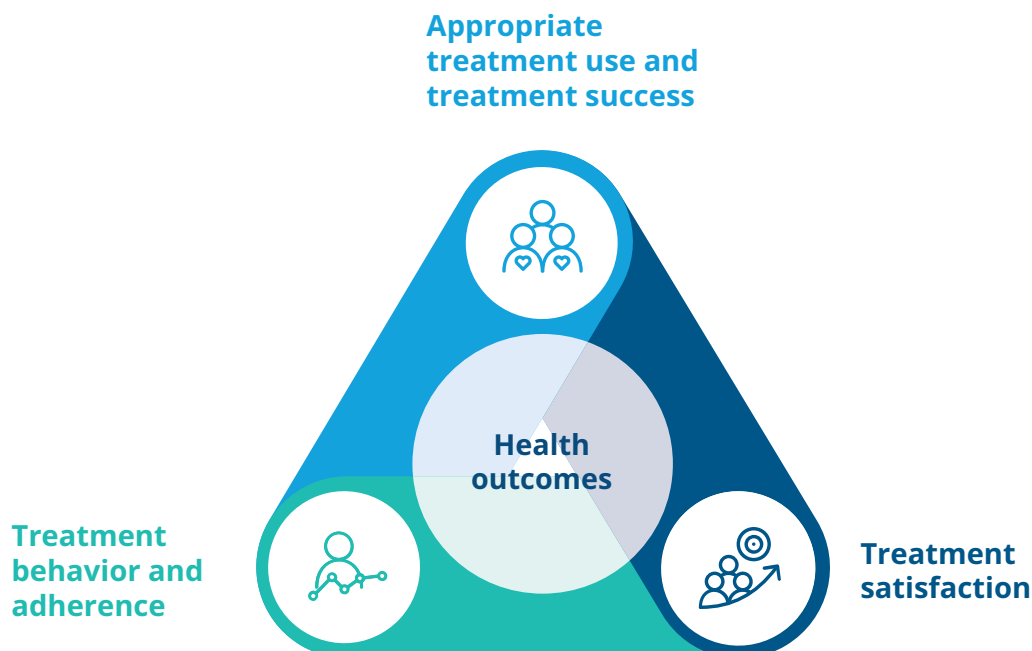
Case study 1

Patient-reported treatment satisfaction is an indicator of medication adherence in patients with multiple sclerosis.

Patients with multiple sclerosis (MS) receiving long-term, subcutaneous interferon β-1b (IFN β-1b; Extavia®) often experience injection-site reactions and injection-site pain, which together with other side effects (such as flu-like symptoms) result in suboptimal treatment adherence.[34] Previous studies had reported that the use of auto-injectors facilitated self-administration and improved patient adherence to the treatment.[35,36] A 26-week, open-label, prospective, noninterventional, observational, multi-country, multicenter study was conducted to evaluate patient satisfaction with IFN β-1b treatment, administered using ExtaviPro™ 30G, a new auto-injector, in a real-world setting. The TSQM was administered to patients with MS who had been treated with IFN β-1b or other disease-modifying therapies with a self-administered auto-injector for ≥3 months and who were planned to switch to IFN β-1b treatment administered using ExtaviPro™ 30G as part of routine clinical care. Results showed a significant increase in overall patient satisfaction with IFN-β1b (Extavia®) at Week 26.[34] Furthermore, patient-reported treatment satisfaction with the effectiveness, side effects and convenience of medication also improved significantly. This reported increased treatment satisfaction may support better adherence to the treatment.

Case study 2

Measuring treatment satisfaction in breast cancer patients shines light on medication adherence patterns.

Adjuvant endocrine therapy (ET) is the standard of care for all women with hormone receptor positive breast cancer (BC). ET reduces the rates of mortality, local recurrence and new primary BCs. However, non-adherence to adjuvant ET is common. Learning the patient-reported reasons for treatment non-persistence may help with the development of interventions to improve adherence to ET.

A study of women with BC receiving ET was conducted to determine the associations between psychosocial factors and ET non-persistence (discontinuation).[37] Eighteen percent of BC patients were non-persistent during the first 2 years of ET based on pharmacy record data. Non-persistence was defined as a ≥90-day gap following the date of anticipated completion of any ET prescription. The TSQM was administered at follow-up to measure treatment satisfaction with the ET, and it was found that women who reported higher TS were less likely to discontinue their ET. Measuring treatment satisfaction with medication in BC is especially important because long-term adherence is required for optimal curative treatment of BC with ET.

Adherence to ET has been reported to be associated with belief in the efficacy of the medication and with belief in the benefits of taking prescribed medications more generally. The TSQM was a suitable questionnaire for this study because the instrument measures effectiveness. In addition, its global satisfaction domain includes questions about the belief in medication benefits such as, "Overall, how confident are you that taking this medication is a good thing for you?" and "How certain are you that the good things about your medication outweigh the bad things?"

Treatment satisfaction is a significant determinant of medication adherence that is modifiable and can be improved through interventional strategies.

Case study 3

Patient-reported treatment satisfaction is an important predictor of anti-hypertensive medication adherence in an Ethiopian ambulatory patient population.

The prevalence of hypertension in African countries, including Ethiopia, is increasing,[38,39] and mortality rates of cardiovascular diseases in low- and middle-income countries is much higher than in high-income countries.[40] Understanding potential determinants, including treatment satisfaction, for medication adherence could be used to design programs to improve treatment outcomes.[41]

A cross-sectional study was conducted to evaluate the impact of treatment satisfaction on anti-hypertensive medication adherence in Ethiopia.[41] The TSQM was administered to consented anti-hypertensive patients (≥18 years) who had received at least one anti-hypertensive medication prescription from the same hospital previously.

Results from patient-reported assessments of treatment satisfaction with anti-hypertensive medication showed that lower adherence was associated with treatment dissatisfaction. Poor adherence threatens the potential cardiovascular benefit of treatment with anti-hypertensive medication. This may result in more strokes, myocardial infarctions and cardiovascular mortality.[42,43] Treatment satisfaction is a significant determinant of medication adherence that is modifiable and can be improved through interventional strategies.

Conclusion

Traditional clinical data sources allow us to collect physical, physiological, and biochemical data on patients and treatment efficacy and safety but do not capture all the data about the treatment or the disease. Patient-reported treatment satisfaction with medication may be obtained only from the patient.[44] For this reason, PROs such as the TSQM have become increasingly valuable to clinical research and practice. They can provide meaningful and reliable information on the patient experience of treatment satisfaction, not just with medication, but with procedures and other forms of care, and may be used by regulators, payers, clinical research, and clinical practice to identify the added value of a given treatment from the patient's perspective.

TO LEARN MORE ABOUT THE TSQM AND HOW TO INCLUDE IT IN YOUR RESEARCH, CONTACT US AT TSQM@IQVIA.COM

As treatments extend beyond medications, there is room to expand treatment satisfaction with medication to satisfaction with procedures and other forms of care.

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About the authors

**ANA MARIA RODRIGUEZ
PHD, MSC, PT**
Director, Patient Centered
Solutions, Global Lead RW and
Preference Practice, IQVIA

Dr. Rodriguez is a trained physiotherapist, psychometrician, epidemiologist, implementation science specialist and preference researcher, and is a Director in the Patient Centered Solutions team at IQVIA. She has over 18 years of research experience as a principal investigator at a large Canadian university-affiliated health care center. Her specialties are mixed-method approaches (quantitative and qualitative), psychometrics, patient preference expertise, and modelling approaches for integration of various data sources (clinical, clinician-reported, patient-reported, and digital health assessment). Dr. Rodriguez has a PhD in clinical epidemiology from McGill University, a MSc in rehabilitation sciences/public health at McGill University and is a licensed physical therapist with several years in clinical care research in orthopedics, cardiorespiratory conditions, rheumatology, neurology, and oncology. She specialized in oncology, with a postdoctoral degree in oncology rehabilitation and another one in oncology epidemiology at University of Toronto.
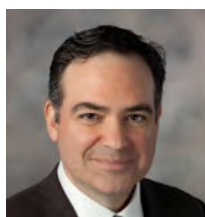
ERIC GEMMEN, MA
Senior Director, Epidemiology, Real
World Solutions, IQVIA

Eric has over 20 years of epidemiologic and outcomes research experience through prospective and retrospective study design and data analyses to support burden of illness, comparative effectiveness and safety, and healthcare resource utilization for IQVIA's Medical Affairs and HEOR clients. His responsibilities at IQVIA have included designing and implementing real-world studies through study concept and protocol writing, directing statistical data analysis and clinical study report writing for Phase IV and observational studies and registries, and providing senior operations oversight to real world effectiveness and safety studies for pharmaceutical, biotechnology, and other health care clients. His work has been published in Pharmacoeconomics, Disease Management & Health Outcomes, and Archives of Internal Medicine, among other journals.

ALEXANDRA PALMER MINTON, MA
Associate Director, Instrument
Services and TSQM Management,
Patient Centered Solutions, IQVIA

Alexandra is a Medical Anthropologist with an interdisciplinary background in qualitative research methods, data analysis and interpretation, cross-cultural perspectives and practice, project management, and team leadership. In her current role, Alexandra is responsible for overseeing the day-to-day business and scientific operations of the IQVIA-owned clinical outcome assessments, including the Treatment Satisfaction Questionnaire for Medication. Prior to joining IQVIA, Alexandra held research positions in the department of Cardiology at both Brigham and Women's Hospital and Beth Israel Deaconess Medical Center, where she was published in the Journal of Thrombosis and Thrombolysis for her work in coronary angiography.

LOUISE PARMENTER, MSC, PHD
Vice President & General Manager,
Global Head, Scientific Services,
Real World Solutions, IQVIA

Louise has broad experience in Real World Evidence (RWE) generation and dissemination leading cross-functional teams that are diverse across cultures and geographies. Louise's current role is Vice President & General Manager, Global Head, Scientific Services, Real World Solutions at IQVIA. She leads a team of epidemiologists, health economics and outcomes researchers; biostatisticians and programmers; data managers and database specialists that deliver the full spectrum of RWE studies. She has been an active presenter at real-world and late-phase conferences and has delivered training, webinars and workshops on all aspects of real-world and late phase research. She is an author of the current ISPOR Code of Ethics and is on the editorial board of Value and Outcomes Spotlight.

CONTACT US

TSQM@iqvia.com

iqvia.com