



START WITH THE END IN MIND

SCREENERS & TOOLS FOR CLINICAL PRACTICE

Mapi Values is the global leader in the international development, validation, and analysis of patient-reported outcomes (PROs), and has extended its leading position in PRO instruments to include the development of decision-making tools.

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CONCEPT AND THERAPEUTIC AREA	EXPERIENCE	
Contributing to clinical decision-making (cont.)		
Validation of the Asthma Control Questionnaire (ACQ) using trial data	> Challenge	Differentiation of patients with well-controlled and poorly controlled asthma is needed to adapt treatment, enrol patients in clinical trials and assess achievement of treatment goals
	> Solution	Use a PRO questionnaire to score the level of asthma control
	> Project	Calibration of the ACQ and categorisation of patients as 'well controlled' or 'not well controlled'
	> Publications	<i>Abetz L, et al. ACAAI, 2004.</i> <i>Juniper EF, et al. Respir Med, 2005.</i>
Convenience of anticoagulant therapy in atrial fibrillation	> Challenge	New anticoagulant treatments are expected to simplify the management of patients
	> Solution	Identify patients who would benefit from new anticoagulant therapies
	> Project	Develop a questionnaire to predict success of switching from vitamin K antagonists to a new oral treatment in atrialfibrillation patients
	> Publications	<i>Arnould B, et al. ISPOR, 2005.</i>
Severity assessment and diagnosis of ocular surfaced is ease (OSD)	> Challenge	Patients with dry eyes are frequently inadequately treated, mainly because of lack of recognition of the impact of the disease and difficulties in diagnosis
	> Solution	Develop disease awareness and support diagnosis of OSD
	> Project	Development and validation of two questionnaires, OSD-QoL [®] and OSD-Med [®]
	> Publications	<i>Baudouin C, et al. ARVO, 2002.</i> <i>Rigeade MC, et al. SFO, 2002.</i> <i>Baudouin C, et al. J Fr Ophtalmol, 2003.</i> <i>Baudouin C, et al. SFO, 2003.</i>
Neuropathic pain sensations	> Challenge	Under diagnosis of neuropathic pain results in inappropriate treatment decisions
	> Solution	Differential diagnosis to discriminate between patients with neuropathic pain and non-neuropathic pain before a treatment decision is taken
	> Project	Validation of the Dutch version of the DN4 including assessment of its psychometric properties and predictive accuracy (on-going)
	> Publications	<i>In preparation</i>

About Mapi Values ...

Mapi Values' mission is to design and perform health economic and PRO projects to demonstrate and communicate the real value of healthcare and services to patients, prescribers, budget-holders and policy-makers, while developing and meeting the needs of all of our stakeholders.

Mapi Values is a member of the Adelphi Group and Mapi Group and was established in 1993. Mapi Values has experienced continuous growth since that time and now employs close to 90 staff in offices in the USA, UK, France and the Netherlands. Our ability to provide international outcomes services is strengthened by our association with Adelphi Targis in Barcelona and Tokyo and our affiliation with the Mapi Research Trust.

Mapi Values can justifiably claim to offer one of the world's finest internal task forces. Our multidisciplinary international team includes physicians, pharmacists, health psychologists, health economists, epidemiologists, statisticians, linguists and public health experts. Through our continued involvement with the FDA and the EMEA on PRO, we offer extensive experience in regulatory submissions. We are also well placed to offer compelling outcomes arguments to help optimize labelling, pricing, reimbursement and product uptake worldwide.

Mapi Values PRO Team

Our PRO team includes a number of individuals with extensive experience in the strategic, regulatory and technical aspects of PRO research:

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Mapi values has a team of 90 people dedicated to health and economic outcomes

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CONCEPT AND THERAPEUTIC AREA	EXPERIENCE
Revealing the patient reality	
HRQoL in haemophilia	<ul style="list-style-type: none"> > Challenge Clinicians lack a tool to provide consistent assessment of haemophilia patients' perceptions throughout their whole life > Solution To develop a measure that can monitor health-related quality of life (HRQoL) of haemophilia patients from early childhood to adult life > Project Development and validation of a haemophilia age-group specific HRQoL questionnaire > Publications <i>Trudeau E, et al. ISPOR, 2003.</i> <i>Guérois C, et al. Hemophilia, 2006.</i> <i>Guérois C, et al. ISOQOL, 2007.</i>
Assessment of the severity of stress urinary incontinence	<ul style="list-style-type: none"> > Challenge Frequency of urinary leakage is not sensitive to treatment in stress urinary incontinence > Solution Adjustment factors, such as anticipation, limitations and other adaptation behaviors, are important to describe the patient's health status and to detect changes in severity > Project Development of a questionnaire assessing the control of urinary leakage risk in activities of daily life > Publications <i>Arnould B, et al. ISPOR, 2006.</i>
HRQoL in GERD	<ul style="list-style-type: none"> > Challenge Patient complaints are a key determinant of care decisions in the management of gastroesophageal reflux disease (GERD), but clinicians lack tools to assess them > Solution Use a brief HRQoL questionnaire to monitor the impact of symptoms on patients' lives > Project Development and validation of the short form of REFLUX-QUAL[®], a GERD-specific HRQoL questionnaire > Publications <i>Amouretti M, et al. JFPD, 2002.</i> <i>Amouretti M, et al. JFPD, 2004.</i> <i>Amouretti M, et al. AGA, 2004.</i> <i>Amouretti M, et al. Gastroenterol Clin Biol, 2005.</i>
HRQoL in COPD	<ul style="list-style-type: none"> > Challenge Existing HRQoL questionnaires in chronic obstructive pulmonary disease (COPD) are not adapted for use in clinical practice and large real-life studies > Solution A new, short tool covering all domains of HRQoL is needed > Project Development and validation of the Visual Simplified Respiratory Questionnaire (VSRQ[®]) > Publications <i>Tonnel AB, et al. ERS, 2005.</i> <i>Arnould B, et al. SMDM, 2005.</i>
Shortness of breath in COPD	<ul style="list-style-type: none"> > Challenge Spirometry parameters do not adequately reflect the actual severity of shortness of breath in patients with COPD > Solution Assess the limitations in patients' everyday activities resulting from shortness of breath > Project Development of a shortness of breath in daily activities severity scale to monitor patients' disease evolution and the impact of treatment on shortness of breath > Publications <i>Arnould B, et al. ISPOR, 2005.</i>
HRQoL in glaucoma and ocular hypertension	<ul style="list-style-type: none"> > Challenge Glaucoma is a silent disease and the majority of patients treated for ocular hypertension complain about the treatment, not about the disease > Solution Provide the ophthalmologist with a way to detect abnormal distress levels in their patients > Project Development of a short version of the Glau-QoL[®] questionnaire to assess the psychological as well as functional impact of the disease > Publications <i>Brouquet Y, et al. ISOQOL, 2002.</i> <i>Zanlonghi X, et al. J Fr Ophthalmol, 2003.</i>

Standardising the assessments	
Assessment of treatment outcome in stress urinary incontinence	<ul style="list-style-type: none"> > Challenge The assessment of treatment success in stress urinary incontinence is difficult in clinical practice because of the multiplicity of criteria and the importance of the patient's subjective view > Solution Standardise and elicit the clinician's global impression > Project Development of a composite scale (symptom, functional impact and satisfaction) for global guided assessment > Publications <i>Arnould B, et al. SMDM, 2005.</i> <i>Costa P, et al. AFU, 2006.</i>
Description and diagnosis of ocular pain	<ul style="list-style-type: none"> > Challenge Inadequate interpretation of acute or chronic ocular pain may result in inappropriate treatment and permanent eye damage > Solution Standardised description of pain perceptions can improve diagnosis and treatment > Project Development and validation of the ODEON[®] questionnaire to assess and describe ocular pain > Publications <i>Colin J, et al. SFO, 2002.</i> <i>Bassols A, et al. SFO, 2003.</i> <i>Colin J, et al. J Fr Ophthalmol, 2004.</i> <i>Arnould B, et al. ISPOR, 2005.</i>

CONCEPT AND THERAPEUTIC AREA	EXPERIENCE	
Standardising the assessments (cont.)		
Pain assessment in people with visual impairment or blindness	> Challenge	The standard assessment of pain is routinely performed with visual analogue scales (VAS), which are not suitable for patients with visual impairment or blindness
	> Solution	Adapt the concept of VAS: switch from a visual scale to a scale using the sense of touch
	> Project	Development and validation of the Senscale®, a sensitive analogue scale measuring pain intensity
	> Publications	<i>Ginies P, et al. Douleurs, 2003.</i> <i>Ginies P, et al. Congrès Douleur, 2003.</i>

Communicating to patients		
Beliefs and expectations regarding insulin therapy in type 2 diabetes	> Challenge	Although insulin therapy is well accepted by patients with symptomatic diabetes, initiation is often delayed in less severe patients
	> Solution	Assess patient barriers to insulin therapy and deliver appropriate messages to the patients
	> Project	Development and validation of a questionnaire assessing the attitudes (positive and negative expectations regarding insulin and injection) of patients with type 2 diabetes
	> Publications	<i>Arnould B, et al. ISPOR, 2005.</i> <i>Arnould B, et al. ISPOR, 2006.</i> <i>Arnould B, et al. ISOQOL, 2007.</i>
Long-term adherence to specific immunotherapy treatment	> Challenge	Major limitations in long-term adherence to treatment hinders the efficiency of sublingual immunotherapy (SLIT) in allergic patients
	> Solution	Detect patients showing limited motivation to persist with treatment and take appropriate communication steps to restore compliance
	> Project	Development and validation of the QUARTIS®, a clinical tool to monitor allergic patients during SLIT (symptom severity, treatment expectations, satisfaction, and intentions)
	> Publications	<i>Arnould B, et al. ISPOR, 2005.</i> <i>Arnould B, et al. SMDM, 2005.</i> <i>Arnould B, et al. ISPOR, 2006.</i>
Compliance in hypertension	> Challenge	Compliance with medication is a limitation to treatment effectiveness, as patients often have negative attitudes towards taking medication, especially if they have asymptomatic diseases, such as hypertension
	> Solution	Detect noncompliant and nonpersistent patients and deliver appropriate messages to them
	> Project	Development of a compliance and persistence screener in patients with hypertension at risk for cardiovascular events
	> Publications	<i>Rosa K, et al. ISPOR, 2006.</i>

Contributing to clinical decision-making		
Asthma control in children	> Challenge	Inappropriate asthma control in children increases the risk of hospitalisation
	> Solution	Allow patients to self-assess their control level
	> Project	Validation of the pediatric form of the Asthma Control Test (ACT®)
	> Publications	<i>Liu AH, et al. J Allergy Clin Immunol, 2007.</i>
Disability in COPD	> Challenge	The treatment decision in COPD depends on multiple factors, including an assessment of needs
	> Solution	Provide the general practitioner with a tool to detect disability in patients with COPD
	> Project	Development of a specific measure of disability in order to optimize the management of COPD
	> Publications	<i>Arnould B, et al. ISOQOL, 2007.</i>
Symptom description in upper gastro-intestinal disorders	> Challenge	The response to proton pump inhibitors is not as good in real life as it is in clinical trials
	> Solution	Improved treatment decisions by detecting patients with a higher level of response
	> Project	Development, scoring and validation of a detailed description of upper gastrointestinal disorder symptoms
	> Publications	<i>Arnould B, et al. ISOQOL, 2007.</i>
Differential diagnosis of urinary disorders	> Challenge	Appropriate treatment decisions in urinary disorders depend on a correct diagnosis
	> Solution	A standardised and comprehensive assessment of urinary symptoms can support differential diagnosis
	> Project	Development and validation of a unique, easy to use, urinary symptom scale for patients with urinary disorders (stress urinary incontinence, overactive bladder and low stream), the Urinary Symptoms Profile (USP®), to assess severity and support differential diagnosis
	> Publications	<i>Arnould B, et al. ISPOR, 2005.</i> <i>Grise P, et al. SIFUD, 2005.</i> <i>Richard F, et al. AFU, 2005.</i> <i>Coloby P, et al. SIFUD, 2006.</i> <i>Arnould B, et al. SMDM, 2006.</i> <i>Arnould B, et al. ISOQOL, 2007.</i>