

QUALITATIVE PATIENT RESEARCH:

The cornerstone for developing
valid endpoints and meaningful
arguments with patient insight

Mapi Values' European experience

Mapi Values is the global leader in the international development, validation, and analysis of patient-reported outcomes (PROs) with a specific expertise in qualitative patient research.



Demonstrate the content validity of an endpoint for clinical research and regulatory submission

<h2>Pain Control</h2>	<ul style="list-style-type: none"> > Challenge: New drugs developed to provide good control of pain over 24 hours need adequate endpoints to demonstrate superiority and differentiate from current standards > Solution: Define the value of 24-hour chronic pain control from the patient perspective to support the selection of PRO endpoints > Project: Thirty patient interviews conducted in France, Germany and UK to develop a conceptual framework for assessment of 24-hour control of chronic pain > Publications: <i>Guillemin I, et al. ISPOR 2008, Athens, Greece.</i>
<h2>Satisfaction in VTE and Atrial Fibrillation</h2>	<ul style="list-style-type: none"> > Challenge: To demonstrate advantages of a new anticoagulant in trials designed to show non-inferiority on clinical endpoints > Solution: Measure patients' satisfaction and convenience with treatment in phase III randomised open-label clinical trials > Project: In all, more than 100 patient interviews were conducted to define the conceptual content of the Perception Anti-Coagulant Treatment Questionnaire (PACT-Q®) and test it for comprehension in 14 languages > Publications: <i>Prins MH, et al. ISTH 2007, Geneva, Switzerland. (2 posters).</i> <i>Prins MH, et al. SMDM 2006, Birmingham, United-Kingdom.</i>
<h2>Urinary incontinence warning time</h2>	<ul style="list-style-type: none"> > Challenge: In urinary incontinence the clinical concept of "warning time" needs to be translated into patient benefit > Solution: Explore the meaning of urgency from a patient perspective > Project: An iterative process of confirmatory interviews with 51 patients was conducted to redefine the concept of urgency and develop a measurement instrument. This was used as an endpoint in clinical trials to show drug superiority > Publications: <i>Zinner N, et al. International Journal of Clinical Practice, 2006.</i>
<h2>Severity of stress urinary incontinence</h2>	<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 behaviours are important to describe the patient's health status and to detect changes in severity > Project: Exploratory and confirmatory interviews with 20 patients were conducted to illustrate the concept, refine the list of activities and word the items > Publications: <i>Arnould B, et al. ISPOR 2006, Copenhagen, Denmark.</i>
<h2>Shortness of breath in COPD</h2>	<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: Thirty-two patients were involved in the development of a shortness of breath in daily activities severity scale to monitor disease evolution and the impact of treatment > Publications: <i>Arnould B, et al. ISPOR 2005, Florence, Italy.</i>
<h2>Influenza vaccination acceptability</h2>	<ul style="list-style-type: none"> > Challenge: Difficult to compare local side-effects of different vaccine injection systems and their impact on acceptability and subjects' willingness to be vaccinated > Solution: Development of a questionnaire to assess importance and acceptability of injection site reactions from the subject's perspective > Project: Thirty-three subject interviews in US, Germany and France were conducted to develop the Vaccinees' Perception of Injection (VAPI®) for inclusion in international clinical trials > Publications: <i>Chevat C, et al. ISPOR 2007, Dublin, Ireland.</i>
<h2>Cough and sputum impact</h2>	<ul style="list-style-type: none"> > Challenge: Cough and sputum production may contribute significantly to patients' impaired well being and functioning in patients with COPD and chronic bronchitis > Solution: Development of a questionnaire measuring cough and sputum symptoms and their impact on everyday life > Project: Forty-one patient interviews in France, Germany, Spain, the US and Japan were conducted to develop the Cough and Sputum Assessment Questionnaire (CASA-Q®) > Publications: <i>Crawford B, et al. Respiratory Medicine, 2008.</i>

Translate clinical advantage into patient benefit

Cataract surgery perceived benefit

- > Challenge: To understand the benefits perceived by patients of being free from glasses after undergoing cataract or presbyopia surgery to receive multifocal implants
- > Solution: Conduct specific studies with appropriate endpoints capturing the patients' perspective
- > Project: Eleven patient interviews exploring the value of living free from glasses were conducted and used to develop a specific satisfaction questionnaire, the Freedom from Glasses Value Scale (FGVS®), in French and Spanish
- > Publications: *Arnould B, et al. ISPOR 2007, Cartagena, Colombia.*
Arnould B, et al. ISPOR, 2008, Toronto, Canada.

Fibromyalgia impact

- > Challenge: The reality of the condition of patients suffering from fibromyalgia needs to be communicated to various audiences
- > Solution: Explore the impact of fibromyalgia on patients' quality of life and functioning
- > Project: Six focus-group sessions with 48 women diagnosed with fibromyalgia were conducted to elicit concepts and ideas to assess the impact of fibromyalgia on their lives
- > Publications: *Arnold LM, et al. Patient Education and Counseling, 2008.*

Raise awareness and determine unmet needs in clinical practice

Satisfaction in Glaucoma

- > Challenge: Glaucoma is a silent disease and there is a risk of patients stopping treatment due to its inconvenience
- > Solution: To detect patients at greatest risk of stopping their treatment
- > Project: Fifteen interviews were conducted to support the development of a questionnaire to assess patient satisfaction and compliance with eye-drop treatment; the EDSQ®
- > Publications: *Nordmann JP, et al. BMC Health Services Research, 2007.*
Berdeaux G, et al. ISPOR 2006, Copenhagen, Denmark.

Description and diagnosis of ocular pain

- > 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: Twenty patients suffering from acute or chronic painful ophthalmic diseases were interviewed to identify wording used to describe ocular pain
- > Publications: *Colin J, et al. SFO 2002, Paris, France.*
Bassols A, et al. SFO 2003, Paris, France.
Colin J, et al. Journal Français d'Ophtalmologie, 2004.
Arnould B, et al. ISPOR 2005, Florence, Italy.

Disability in COPD

- > Challenge: The treatment decision in COPD depends on multiple factors, including an assessment of needs
- > Solution: Provide general practitioners with a tool to detect disability in patients with COPD
- > Project: Ten patient interviews were conducted to develop a specific measure of disability in order to optimise the management of COPD
- > Publications: *Arnould B, et al. ISOQOL 2007, Budapest, Hungary.*

Identification and reduction of gaps between drug activity and patient perception of treatment benefit

HRQoL in glaucoma and ocular hypertension

- > **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 ophthalmologists with a way to detect abnormal distress levels in their patients
- > **Project:** The relevant domains of HRQoL were identified and explored in depth during interviews conducted with 22 patients at all disease severity levels.
- > **Publications:** *Brouquet Y, et al. ISOQOL 2002, Orlando, USA.*
Rouland JF, et al. Journal Français Ophtalmologie, 2002.
Zanlonghi X, et al. Journal Français Ophtalmologie, 2003.
Béchetoille A, et al. Acta Ophthalmologica Scandinavica, 2007.

Long-term adherence to specific immunotherapy treatment

- > **Challenge:** Major limitations in long-term adherence to treatment hinder the efficiency of sublingual immunotherapy (SLIT) in allergic patients
- > **Solution:** Detect patients who show limited motivation to persist with treatment and take appropriate communication steps to restore compliance
- > **Project:** Forty-six patient interviews were conducted to develop the QUARTIS[®], a clinical tool to monitor symptom severity, treatment expectations, satisfaction and intentions in patients during SLIT
- > **Publications:** *Arnould B, et al. SMDM 2005, San Francisco, CA, USA.*
Arnould B, et al. ISPOR 2005, Florence, Italy.
Arnould B, et al. ISPOR 2006, Copenhagen, Denmark.

Some examples of Mapi Values recently published experience, gained through thousands of patient interviews conducted over more than 15 years of Quality of Life and Patient-Reported Outcomes Research.

A dedicated international team of sociologists, psychologists, trained interviewers and analysts.

Contact us for your Patient-Reported Outcomes qualitative research

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