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# Patient Reported Outcomes: An Overview



## Synopsis

Patient reported outcomes (PROs) are a measurement based on a report that comes directly from the patient about the status of their health condition without amendment or interpretation of the patient's response by a clinician or anyone else. Valid and reliable PRO instruments are able to provide a standardized, quantifiable measure of treatment benefit, upon which the outcomes of interventions and treatment effect from the patient's perspective can be judged. In some instances, PROs provide the best evidence of a treatment's effectiveness, for example when evaluating treatments for pain, gastrointestinal and urological symptoms, or psychological well-being. This book aims to provide an overview of PRO applications, methodology and validation in order to help reader approach this measurement that are playing an increasingly central role in drug development decision making.

## Book Information

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## Customer Reviews

Dr Annabel Nixon is a Patient Reported Outcomes expert with 19 years' international experience in this field. Dr Nixon has specialist knowledge of FDA, EMA and health technology agency requirements for Patient Reported Outcomes and other clinical outcome assessments to support label claims and product reimbursement. Dr Nixon has presented at international conferences and published widely in peer review publications. Previously Dr Nixon completed a PhD at the University of Manchester focused on measurement of health-related quality of life in a Kenyan population, was

a Research Fellow at the London School of Hygiene and Tropical Medicine before moving into consultancy initially at Quintiles located in Europe and the US, followed by Director of the Patient Reported Outcomes group at Oxford Outcomes and subsequently Director of Patient Centered Outcomes at PRMA Consulting. Currently Dr Nixon is working as an independent patient reported outcomes consultant at Chilli Consultancy and is co-chair of the DIA Study Endpoints community. Diane Wild is a researcher with particular expertise in the translation and linguistic validation of patient reported outcome measures. She has published widely in the areas of patient reported outcomes and linguistic validation. She was the lead author on a translation and linguistic validation best practices paper in 2005 which has become the industry standard for methods in this area. Diane was the founding Director of Oxford Outcomes, a multi-national outcomes research consultancy. Currently Diane is working as an independent patient reported outcome and linguistic validation consultant whilst studying for a MSc in Medical Anthropology. Willie Muehlhausen is a recognized eClinical Technology expert with 17 years' experience in this field of clinical research. He has researched and published with a specific focus on usability of patient facing technologies and has developed several medical devices for patient use. In recent years he has focused his research on issues and challenges around the development and migration of electronic Clinical Outcomes Assessments and the implementation of BYOD strategies. From 2011 to 2013 he served as the founding Vice Director of the C-Path's ePRO consortium and still chairs the Scientific Subcommittee. Currently Willie is Head of Innovation at ICON plc where his team develops next generation data capture and analytics systems which include ePRO solutions.

No substantive content.

The book is more than simply an introduction to the field of Patient Reported Outcomes. Apart from providing essential information that would be indispensable for anyone involved in clinical research and drug development on the one hand, and regulatory matters and funding decision-making, on the other hand, it also offers insightful comments about future developments in the field as well as important details about current practices. The book is written in a clear and concise manner not laden with technical jargon, so no special background in the field is necessary for reading and learning from it. It basically gives you all you need if you want a quick and reliable reference about PROs: from their application and data collection, to linguistic validation, ePRO and reporting. The book is written by experts and opinion leaders in the field, so there is no doubt about the quality and validity of the information they share with the readers. Besides, I haven't found

anything even close to this book when it comes to value-for-money.

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