

1. Record Nr.	UNINA9910964672403321
Titolo	ePro : electronic solutions for patient-reported data // edited by Bill Byrom and Brian Tiplady
Pubbl/distr/stampa	Farnham, Surrey, England ; ; Burlington, VT, : Gower, c2010
ISBN	1-315-58014-4 1-317-14191-1 1-317-14190-3 1-282-85767-3 9786612857676 1-4094-1242-3
Edizione	[1st ed.]
Descrizione fisica	1 online resource (297 p.)
Altri autori (Persone)	ByromBill TipladyBrian
Disciplina	610.285
Soggetti	Clinical trials - Data processing Outcome assessment (Medical care) - Data processing
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Cover; Contents; List of Figures; List of Tables; Foreword; About the Editors; List of Contributors; Introduction; 1 Recall Bias: Understanding and Reducing Bias in PRO Data Collection; 2 Cognitive Interviewing: The use of Cognitive Interviews to Evaluate ePRO Instruments; 3 Data Quality and Power in Clinical Trials: A Comparison of ePRO and Paper in a Randomized Trial; 4 Regulation and Compliance; 5 Selection of a Suitable ePRO Solution: Benefit, Cost and Risk; 6 Patient Compliance in an ePRO Environment; 7 Computerized Clinical Assessments 8 Diary Design Considerations: Interface Issues and Patient Acceptability 9 Equivalence Testing: Validation and Supporting Evidence When Using Modified PRO Instruments; 10 ePRO Applications and Personal Mobile Phone Use: Compliance Documentation and Patient Support; 11 Future Developments and Applications: Emerging Technologies and New Approaches to Patients; Index
Sommario/riassunto	Recently, there has been much open debate with the regulators around the use of ePRO in clinical drug submissions. US and European agencies

have approved new drugs that have included ePRO data in the submission dossier, but there are many questions around the adoption of the technology that concern the community. Bill Byrom and Brian Tiplady's ePro addresses these questions, reviews the new FDA guidance, and provides a very contemporary view on this important subject.
