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Conduct Secondary Research"; "2.3 Kick-Off Meeting"; "2.4 Determine Appropriate Target Sites and Participants (Inclusion Criteria)"; "2.4.1 Sample Size"; "2.4.2 Clinical Site and Potential Participant Determination Process"; "2.5 Internal Review Board Requirements for CI"; "2.6 Protocol Development"; "2.6.1 Contents of a Protocol"; "2.6.2 Background and Overview"; "2.6.3 Objectives"; "2.6.4 User Profile or Inclusion/Exclusion Criteria"; "2.6.5 Methods for Data Collection"; "2.6.6 Study Materials Required"; "2.6.7 Data Management Plan"; "2.6.8 Target Schedule"; "2.6.9 Protocol Template Example"; "2.6.10 Toward Rational Design of the Human-Device Interface in Catheter-Based Interventions: A CI Study"; "Unmet Need"; "Project Description"; "Milestones"; "Resources"; "2.7 Conducting a CI Study OUS"; "2.8 Best Practices"; "References"; "3 Contextual Inquiry Methods"; "3.1 Contextual Inquiry Methods"; "3.1.1 Overview"; "3.2 Approaches to Observation"; "3.2.1 Overt Observation Approach"; "3.2.2 Think Aloud Approach"; "3.2.3 Use Simulation with Reflection"; "3.2.4 Role-Playing Approach"; "3.2.5 Note Taking: Specific CI Observational Measures to Consider"; "3.3 Interviews"; "3.3.1 Interviewing Approaches"; "3.3.2 Semi-Structured Approach"; "3.3.3 Unstructured Approach"; "3.3.4 Narrative Interview"; "3.3.5 Good Interview Techniques"; "Establish a Rapport with the Study Participant"; "Know what Questions to Ask"; "Avoid Asking Leading Questions"; "Only ask one question at a time and then wait patiently"; "Avoid Questions that are too Open"; "Include Questions of HOW, WHY, WHEN, FOR WHAT PURPOSE"

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## Sommario/riassunto

Contextual Inquiry for Medical Device Design helps users understand the everyday use of medical devices and the way their usage supports the development of better products and increased market acceptance. The text explains the concept of contextual inquiry using real-life examples to illustrate its application. Case studies provide a frame of reference on how contextual inquiry is successfully used during product design, ultimately producing safer, improved medical devices. Presents the ways contextual inquiry can be used to inform the evaluation and business case of technologyHelps users

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