Protocol Quality Rating Tool (PQRT) for Clinical Trials

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Further information
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OVERVIEW

- PQRT: a tool designed to grade the quality of a clinical trial protocol document
- Each section is evaluated against a 1-9 scale with 1 being the best and 9 the worst
- We hope colleagues from other institutions will evaluate the PQRT to determine its usability in a wider range of IITs and settings.

BACKGROUND

A high-quality protocol document is essential for the successful and efficient implementation of clinical trials, but there is no consensus on how clinical trial protocol document quality should be evaluated. We used a modified Delphi approach and cognitive interviews to develop a new protocol document quality assessment tool, the Protocol Quality Rating Tool (PQRT). We compiled a checklist of elements that should be included in a high-quality trial protocol document and asked experts to rate the importance of each element. We developed the PQRT by describing the expected content of each element and identified essential vs. additional (bonus) content to differentiate high- vs. low-quality protocol documents and then organized the elements into 18 sections. We revised the PQRT based on feedback from and cognitive interviews with our protocol quality rating team. We then tested the PQRT using 10 protocol documents previously approved by the Institutional Review Board. All the protocol quality raters found the tool easy to use and their scores were highly concordant for 8 of 10 protocol documents. We have developed and tested a simple tool to measure clinical trial protocol document quality and encourage other researchers to evaluate and validate it.

ADDITIONAL DETAILS

Explore other available products test at University of Michigan