

Report on Medicare Compliance Volume 31, Number 34. September 19, 2022 Checklist for Implementing, Expanding Research: Reviewing Compliance, Finances, Patient Volume

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The Food and Drug Administration's April draft guidance for diversity in clinical trials is a new area to incorporate, but there are other factors to consider when implementing or expanding research. Here's a checklist to help organizations help think them over. It was developed by PYA in conjunction with Rhonda Paz, Managing Principal of Clinical Trial Administrators. Contact her at rhonda@ctadministrators.org.

1. Organizational Support
a. Is leadership looking for a new revenue opportunity?
b. Is leadership looking for ways to enhance the organization's reputation and/or differentiate it from competitors?
c. Is the organization looking for ways to minimize outmigration and attract new patients?
d. Does the organization desire to achieve or maintain specialized accreditations requiring clinical trial participation?

Clinical Trial Program: Implementation/Expansion Readiness Assessment Checklist

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