Clinical Trial Program:
Implementation/Expansion Readiness Assessment Checklist

The following addresses the elements of an effective clinical trials service line and considerations for implementation and expansion. It is not a comprehensive checklist, and additional factors may need to be considered depending on the maturity of an organization's clinical trials program.

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?

2. Patient Volumes
a. In what specialties/subspecialties does the organization have a critical mass of patients (i.e., oncology, infectious disease, cardiology)?
b. What are the **top five** diagnoses seen by the organization?
c. How many patients are seen annually per the **top five** diagnoses?

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3. Physician Interest and Capability

a. Are there physicians with a strong interest in offering clinical trials to their patient population?

b. Do the providers have a critical mass of patients in their given specialty?

c. Do interested providers have experience in clinical trials, or are they willing to undergo training in how to conduct clinical trials?

4. Infrastructure

a. Is there existing talent with clinical research administration experience, or is the organization prepared to hire research professionals focused on clinical coordination, regulatory processing, and research finance administration?

b. Do clinical research policies and standard operating procedures (SOPs) exist, or is the organization prepared to adopt them?

c. Does the organization have a clinical trial management system and a CFR 21 Part 11 compliant research document storage system, or is it willing to evaluate, select, and implement these systems?

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5. Research Compliance

a. Does the organization have an Institutional Review Board (IRB) approved by the Office of Human Research Protections (OHRP) or an agreement with a commercial IRB to provide regulatory reviews and oversight for human subject research?

b. Are clinical coders and billers knowledgeable about clinical trial billing practices, or are they willing to learn?

c. Does the organization conduct coverage analyses (or have the capability to do so) for new studies?

d. Does the organization have a research conflict-of-interest policy (COI), or is it willing to adopt one?

6. Financial Considerations

a. Has the organization prepared a three- to five-year business plan to guide the clinical trial program development and financial performance expectations?

b. Has the organization established a mechanism to compensate physician research time?

c. Is the organization willing to invest in the start up of a clinical trial program and await a 12- to 18-month return on investment?

d. Does the organization have policies in place to govern research fund management, including reinvestment of profit for continued program growth?

e. Does the organization review clinical trial budgets to ensure they are consistent with fair market value?