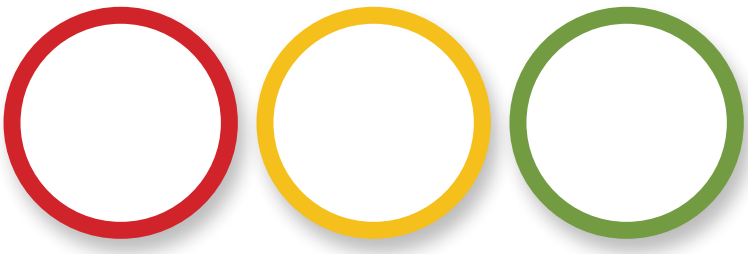
Let's talk Clinical Readiness!

How strong is the compliance focus of your Phase I, II, or III clinical programs?

6 Key Factors play a critical role in bringing you into regulatory compliance and can contribute to maximizing the value of your assets (or potentially put your data at risk if not done correctly).



These are the questions we ask to help navigate compliance throughout the life of your trial.

TriRadial SOLUTIONS

Your Clinical Readiness Navigators

1

Are your processes robust enough to withstand the scrutiny of an inspection?

2

Can you definitively demonstrate sponsor involvement in the decision-making, review, and approval at key decision points in a trial?

- Risk management and mitigation
- Protocol design and feasibility
- Site selection
- Deviations and misconduct

3

Is it clear who is involved in decision-making, and is that part of your process?

Have the right functional experts contributed to the decisions?

4

Do you have easily retrievable evidence of your decision making to provide an auditor or inspector?

Are decision documents filed in a document repository versus buried in email?

5

How do you document your approval of your vendors' decisions and actions?

Do decision logs and minutes clearly outline sponsor involvement, review, and approval?

6

Do your vendor oversight processes adequately support your overall Inspection Readiness plan?

Can you demonstrate your active participation in key decisions made by a vendor?

Have you ensured your vendors are following their procedures?

Are you working as partners with your vendors to ensure mutually successful outcomes?

At TriRadial, we focus on **Clinical Readiness** as a key success factor for your clinical development programs.

We define **Clinical Readiness** as the convergence of **operational efficiency, vendor oversight,** and **regulatory compliance**. It covers the full spectrum of internal and external clinical trial activities, as well as turning **functional collaboration** into an essential building block focused on successfully delivering clinical trials **seamlessly, compliantly, and repeatably.**

Your Clinical Readiness Navigators

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