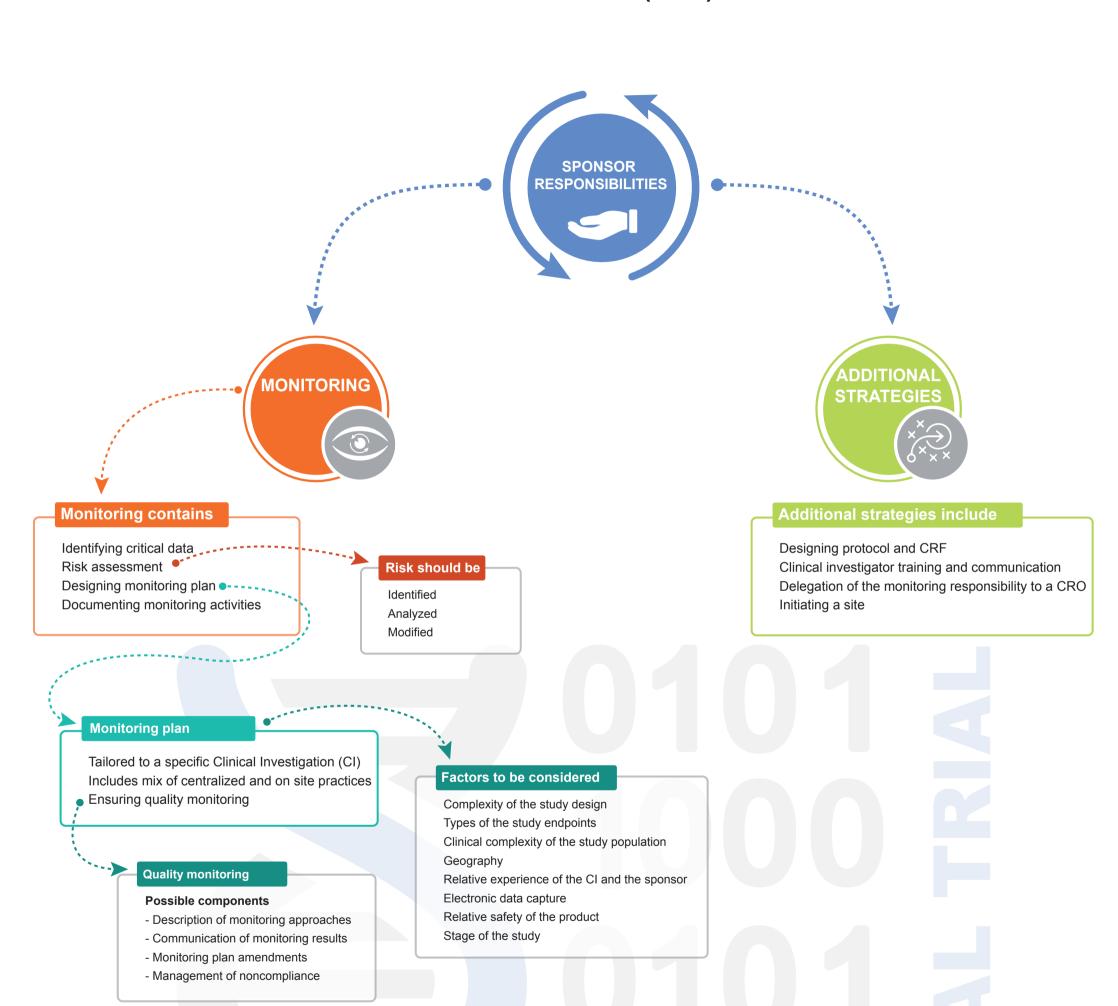


# **GUIDANCE FOR INDUSTRY.**

# OVERSIGHT OF CLINICAL INVESTIGATIONS - A RISK-BASED APPROACH TO MONITORING (FDA)



## **Monitoring methods**

### Centralized monitoring

- Identifies more than 90% on site findings
- Better detects data abnormalities
- Prioritizes on site visits
- Timely identifies higher risk sites
- Supplements or reduces on site visits
- Available due to technological capabilities

#### On site monitoring

- Needed more intensively in CI with no prior experience
- Helpful early in the study