5. REGULATORY & ETHICAL COMPLIANCE

Best practices should appropriately consider global & local regulations and guidance. In doing so they should also adhere to appropriate privacy, consent and sharing guidelines, protect those stakeholders providing sensitive or personal data with safeguards to ensure ethical safety and compliance for patients and care givers.

CONSIDERATIONS AND GUIDANCE

The practice should demonstrate…	Guidance notes
Local health authority vetting and acceptance compliance in the region where it will be utilized	Regulatory Resources: ❑ Global Regulatory Authority Websites by Region
Compliance with relevant Health Authority and International guidance and regulatory requirements	Aligns with all ICH guidelines with main focus on efficacy: ❑ ICH E6-Guideline For Good Clinical Practice ❑ ICH E8-General Considerations For Clinical Trials
Consideration and alignment with any applicable privacy laws	For example, check, verify and prove that the practice does not contravene security rules ❑ (e.g., HIPAA) ❑ Aligns with GDPR guidelines ❑ Aligns with relevant study protocols and subject safety
That it does not lead to additional burden to key stakeholders	Consider specific users ❑ any effect on efficiency or usefulness to the wider audience including but not limited to site staff, patient/subject, sponsor/CRO, ethics committees, vendors, etc.? ❑ Determine level of burden and whether it will lead to safety concerns, ❑ Consider inefficiencies preventing any of the listed group's ability to complete deliverables.