Remote Monitoring & SDV

Feasibility of Remote Monitoring

Site Staff availability and commitment
- Staff may have conflicting priorities
- Commitment to additional resource requirement of remote monitoring
- Time zone considerations

Technology
- Conferencing technology
- Video links (virtual tours)
- External access to internal systems

Competency with technology
- Site staff familiarity with conferencing technology
- CRA training in the navigation of the site systems

Connectivity
- Reliability of link
- Contingency plans if technology fails

Security, Data Protection and Confidentiality
- Security of the technology
- Where will source notes, confidential information be uploaded
- Confidentiality agreements, consent forms
- Location of CRA when accessing source records

Trust
- Do not record interviews
- Do not take screenshots
- Hidden attendees
Access to Source Data

Remote Monitoring & SDV

Opportunities
- No travel time
- Can invite additional SMEs to join
- Leverage eData Systems
- Leverage technology
- CA/EC engagement
- Build into protocol, trial plans and specifications

Risks
- Reduced visibility
- PI less likely to engage with remote MV
- Access to source data
- Security & GDPR concerns
- CA/EC expectations
- Ad hoc deployment