Remote Monitoring & SDV

STEM MEETING 15MAR2021

CATHY DOVE

DOVE QUALITY SOLUTIONS

15Mar2021

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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
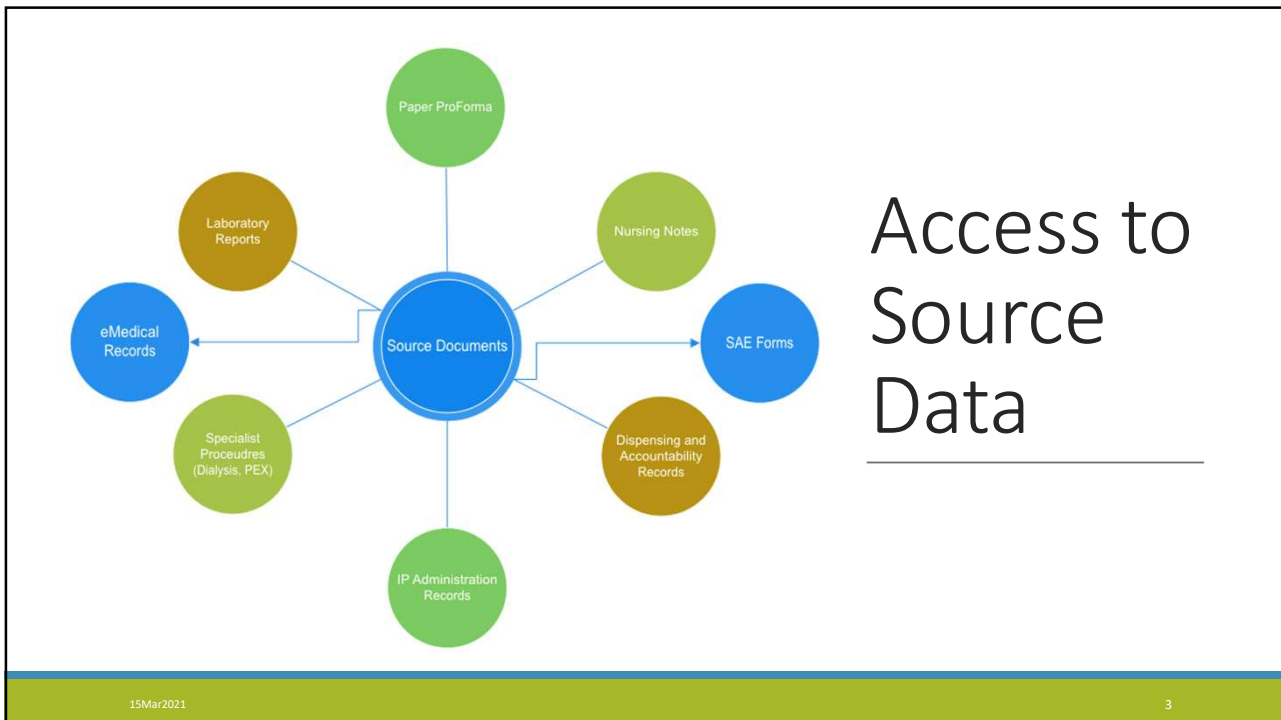◦ Location of CRA when accessing source records

Trust
◦ Do not record interviews
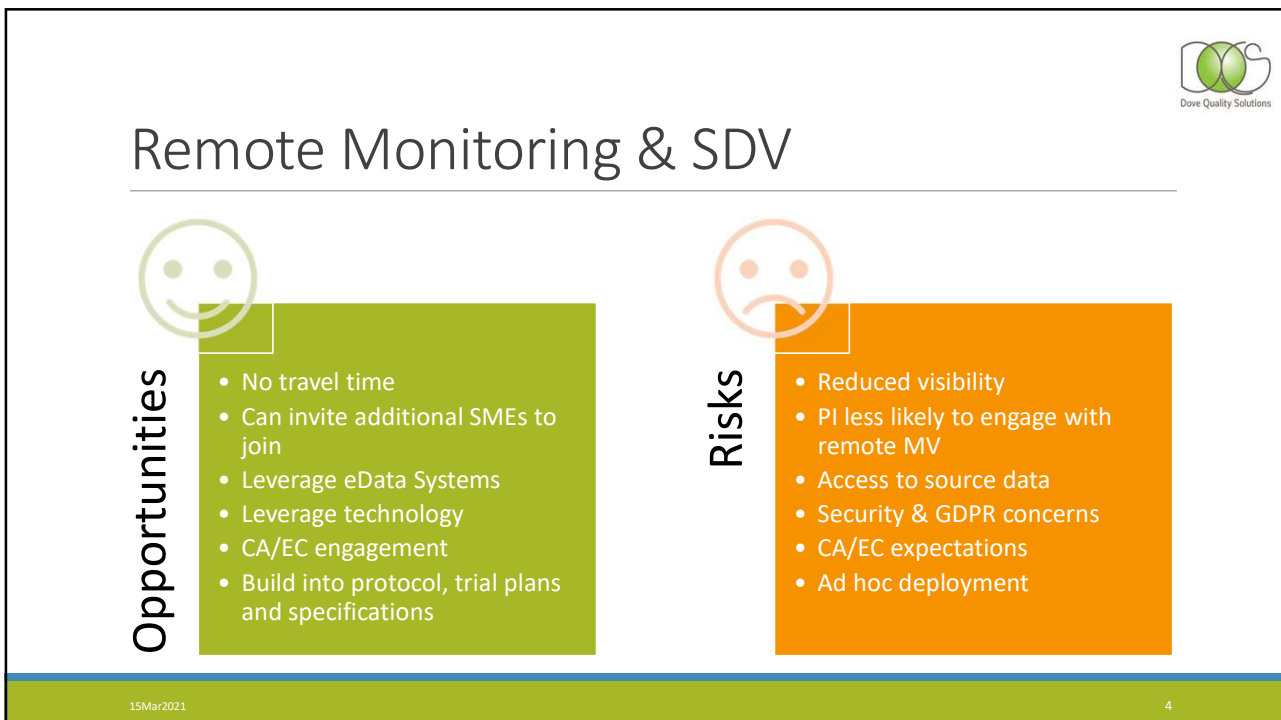◦ Do not take screenshots
◦ Hidden attendees

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Access to Source Data

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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

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