





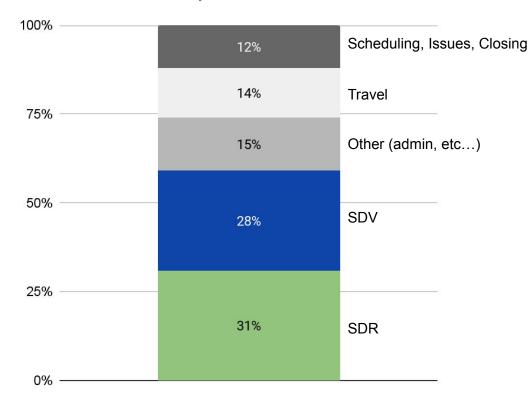
Background of this survey

- CRIO retained a third party market research firm to conduct a web-based survey of Clinical Research Associate (CRA) users with recent log ins to the CRIO system. The firm solicited participation from 16MAR2022 to 30MAR2022 to an anonymous web survey. Participants were given a small stipend for their participation, which was estimated to take 10 minutes.
- A total of 79 responses were received.



CRA's spend most of their time on Source Data Review (SDR), followed closely by Source Data Verification (SDV)

Percent of Time Spent on Tasks



Definitions:

Source Data Review (SDR): Review of source data for protocol and ICH-GCP compliance, ALCOA, etc.

Source Data Verification (SDV): Verification that data entered into EDC matches data captured in source

Other: Miscellaneous tasks not captured elsewhere

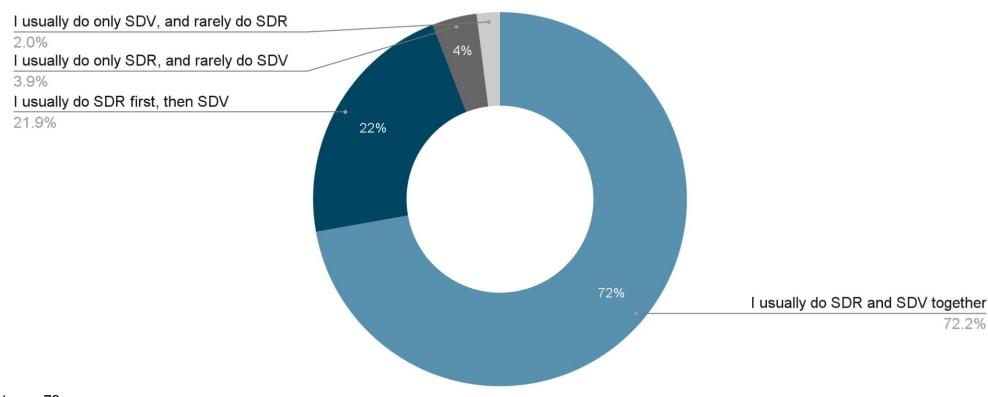
Scheduling, Issues, Closing: Scheduling site visits, issuing follow-up letters and closing out action items

Note n = 79. Totals Sum to 100%.



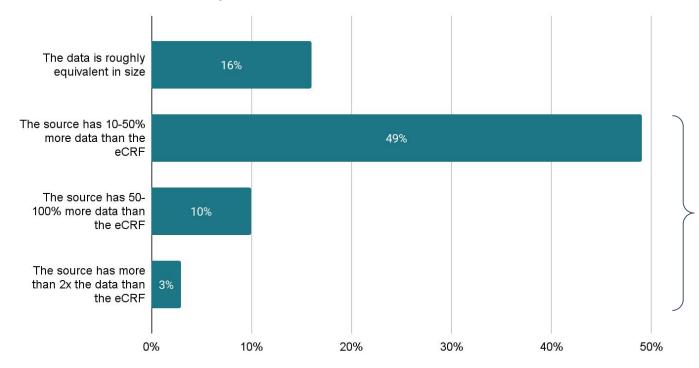
Most of the time, CRA's do SDR and SDV simultaneously; Some do SDR first, then do SDV

Reported Sequence of SDV Completion



CRA's agree that source data is more extensive than eCRF

Source Data Size Compared to eCRF

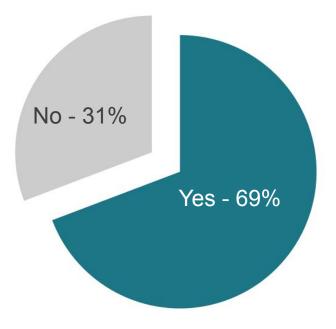


84% of respondents reported that Source has more data points than the eCRF



Most CRA's have done risk-based monitoring that specified less than 100% SDV required

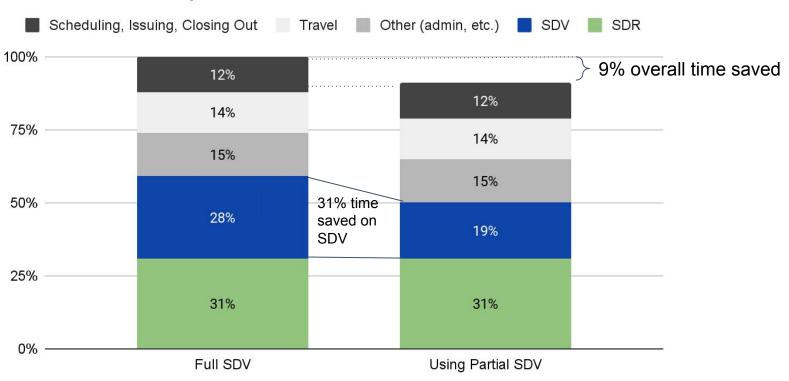
Have you had a recent experience on a trial which risk-based monitoring required you to perform SDV on a subset of data fields?





When doing risk-based monitoring, CRA's reported 31% time savings on the SDV component – 9% overall time savings

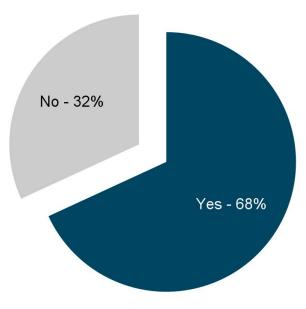
Percent of Time Spent on tasks



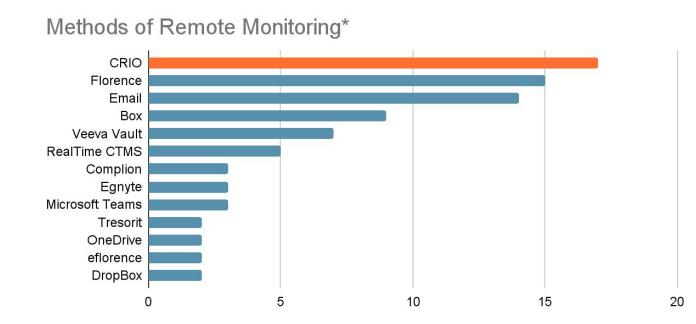


Most CRA's have had experience with remote monitoring – and CRIO was the most commonly cited tool used

Have you had a trial that involved remote monitoring?



Of the 68% that said yes:





CRA's provide positive feedback on CRIO

25%

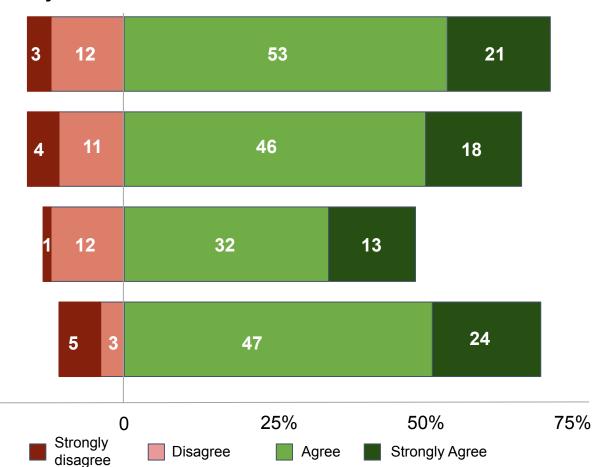
CRIO System Feedback

The CRIO system is easy to use and navigate

The CIRO system helps me perform my job more quickly

The data in the CRIO eSource system is higher quality

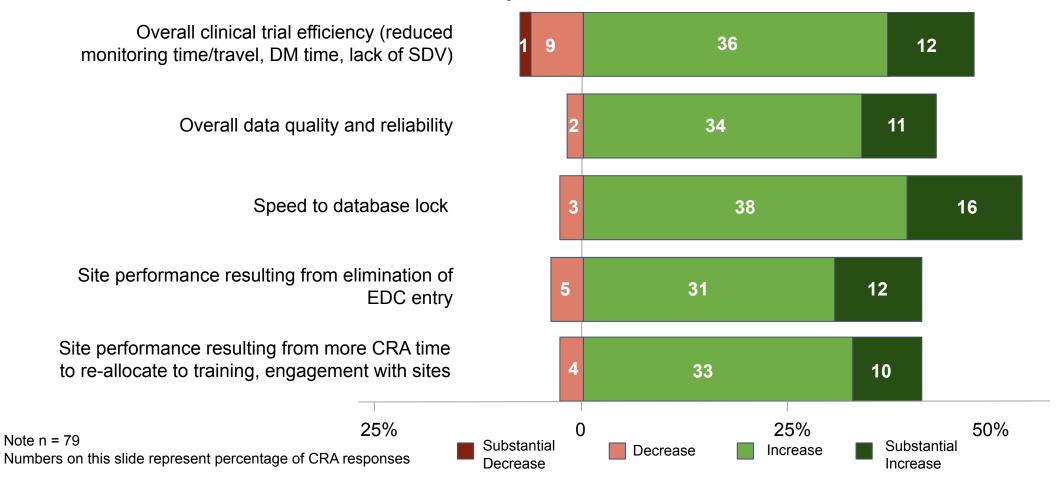
Sponsors would benefit if more sites utilized the CRIO eSource system, or a system like it





CRA's respond very favorably to CRIO's proposed new integrated eSource-EDC data capture model

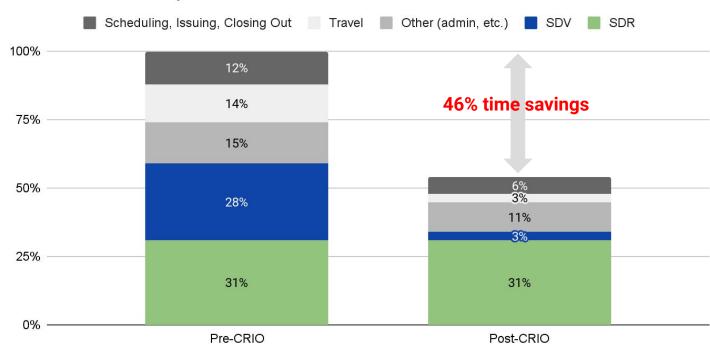
CRIO System Feedback





CRIO's EDC model could generate up to 46% time savings

Percent of Time Spent on Tasks



Assumptions:

- All SDV time spent eliminated except for random elements such as meds reconciliation
- All monitoring visits unnecessary, apart from COV
- No need to document reviews; just go in and issue queries, mark reviewed; move to periodic phone calls for strategic issues