Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

Third Party Vendor Data Management- Collaboration Strategies

Data Manager's Role Beyond Data Point Reconciliation

Disclaimer: The presentation content and specific case studies shared from my work experience/projects handled, hence no assumptions should be made. Please connect for additional details/discussion which can be shared purely based on project confidentiality clauses.

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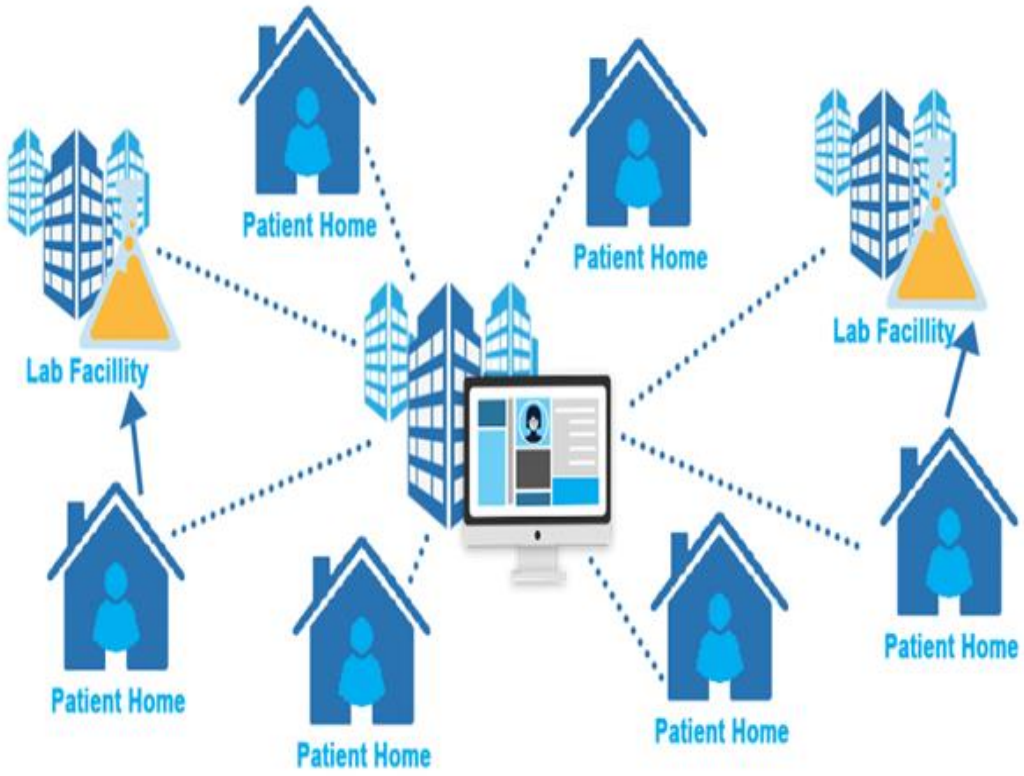
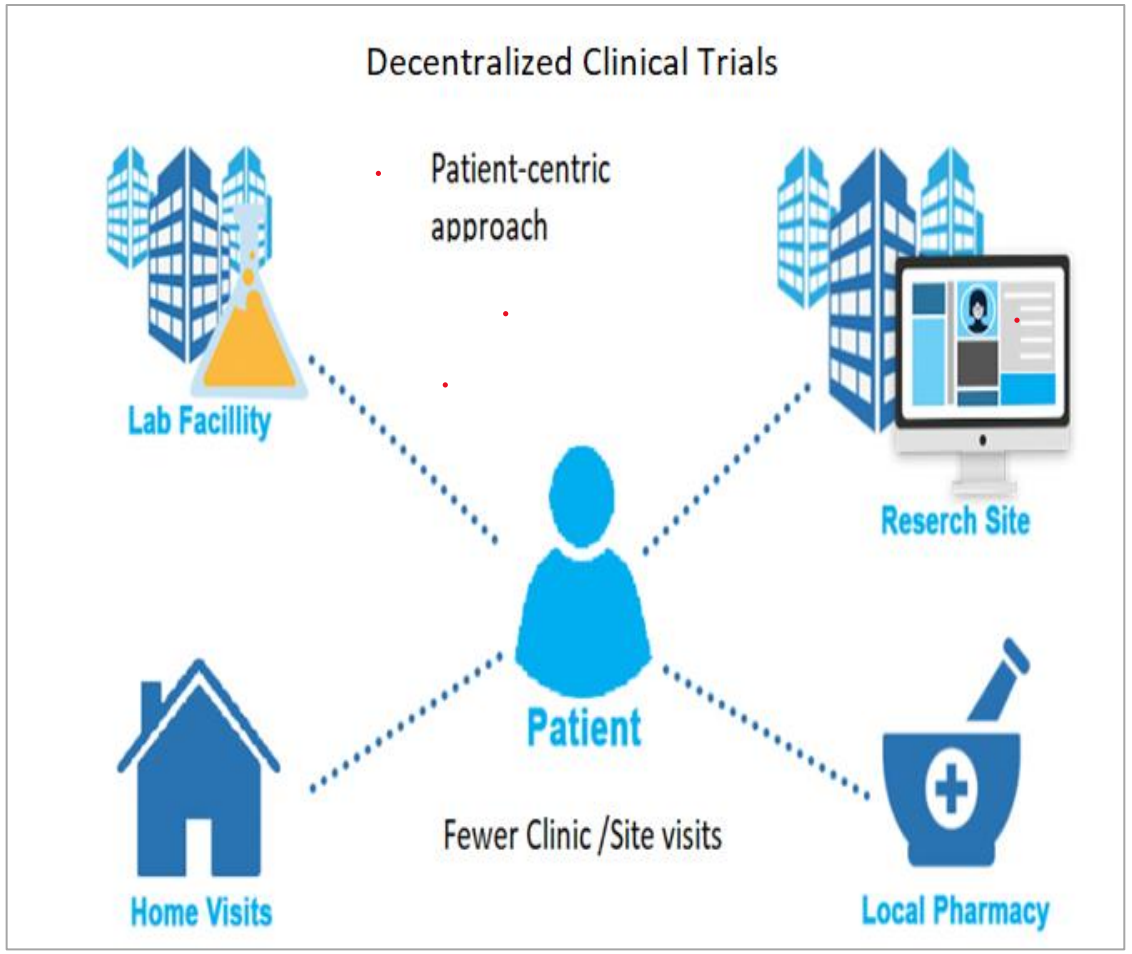
Traditional Clinical Trials and Third-Party Data

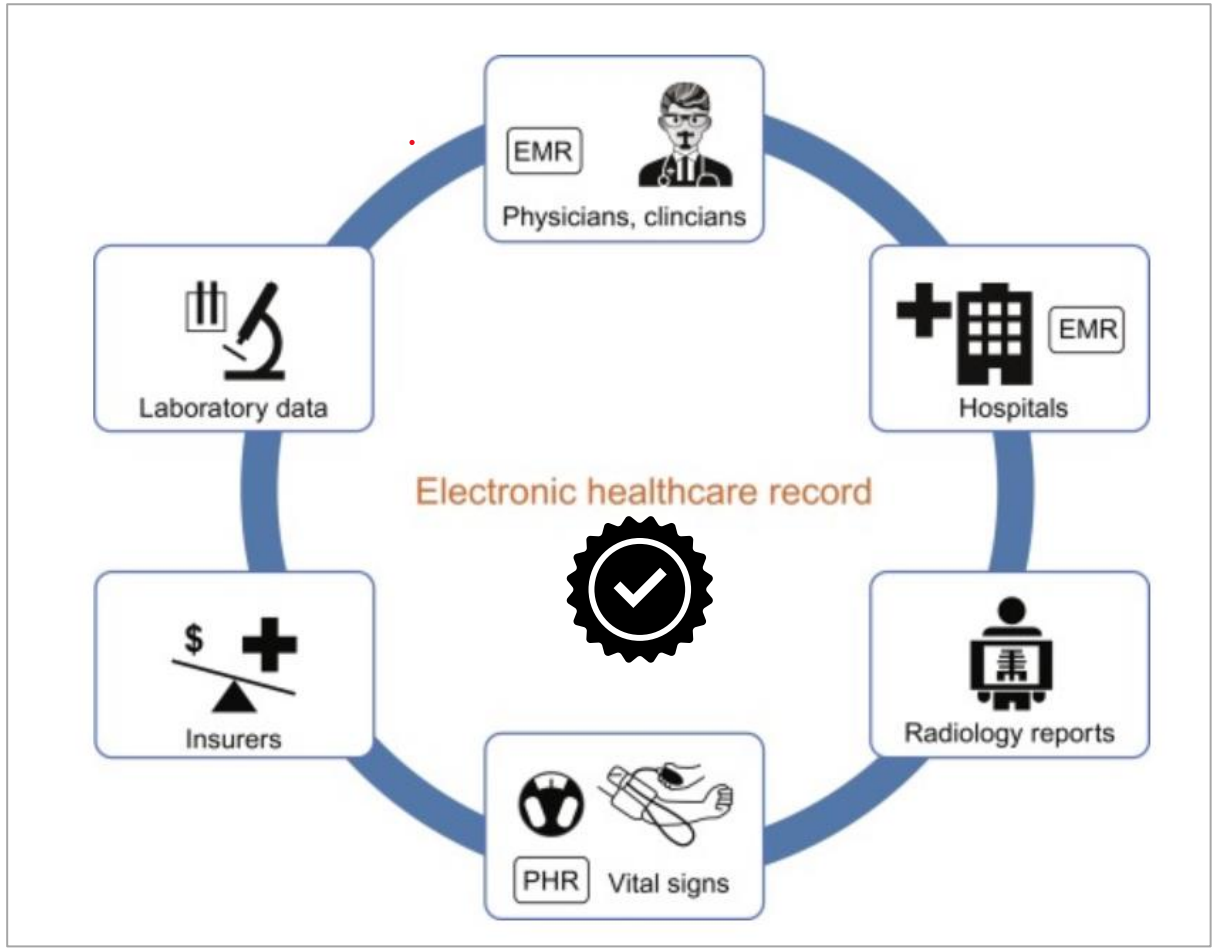
Traditional apporach: Hospital visits for Dosing, check ups, tests and follow ups despite introduction of EDC tools for data collection



Specialized vendors, Pdfs, tracking followed by digitalization of records

Today's Decentralized/Virtual Trials





Third Party Data Today and Future

Specialized Labs working as One stop solutions for specialized Sample analysis minimizing need of mulitple sample collections and analysis centres

Ease of sampling/Painless procedures
Mobile collection units/Local submissions
Point to point pick ups from Patient homes

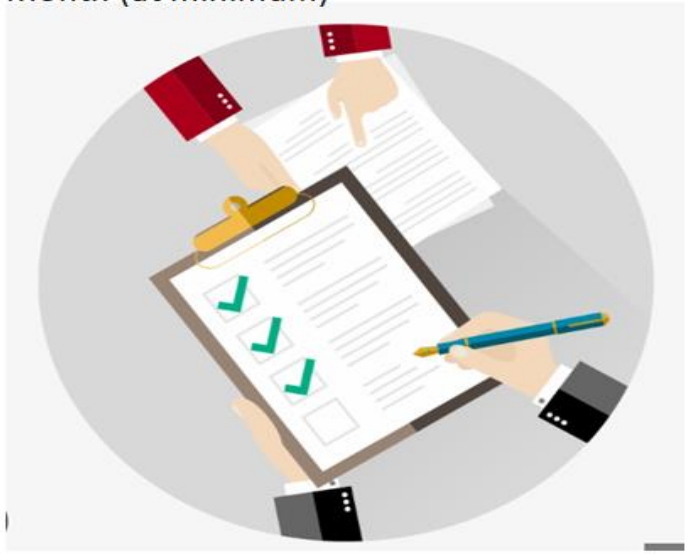
All parties accessing same data, audio, video access, consults

Constant Real Time monitoring without need of hospital Visits and direct access to Digital records

Is Data Manager's Participation Enough?

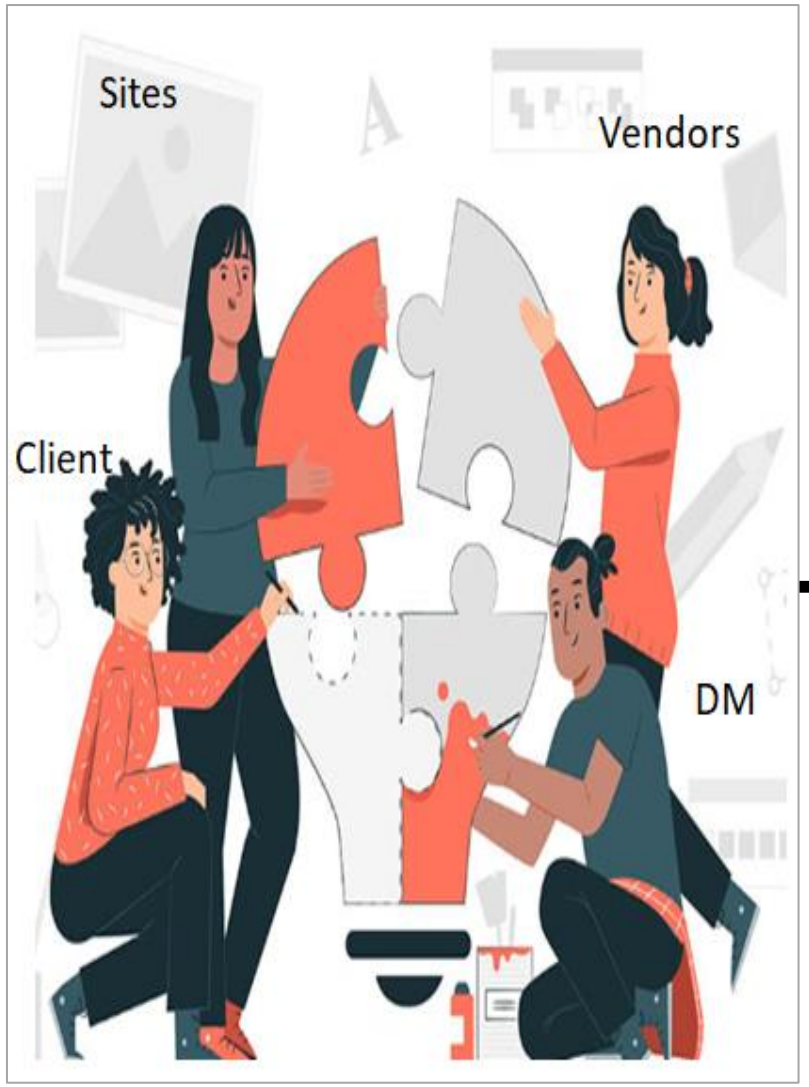
File format, Minimum identifiable data points to match records in EDC Vs vendor file

Review of Matches/Mismatches Once a Month (at minimum)

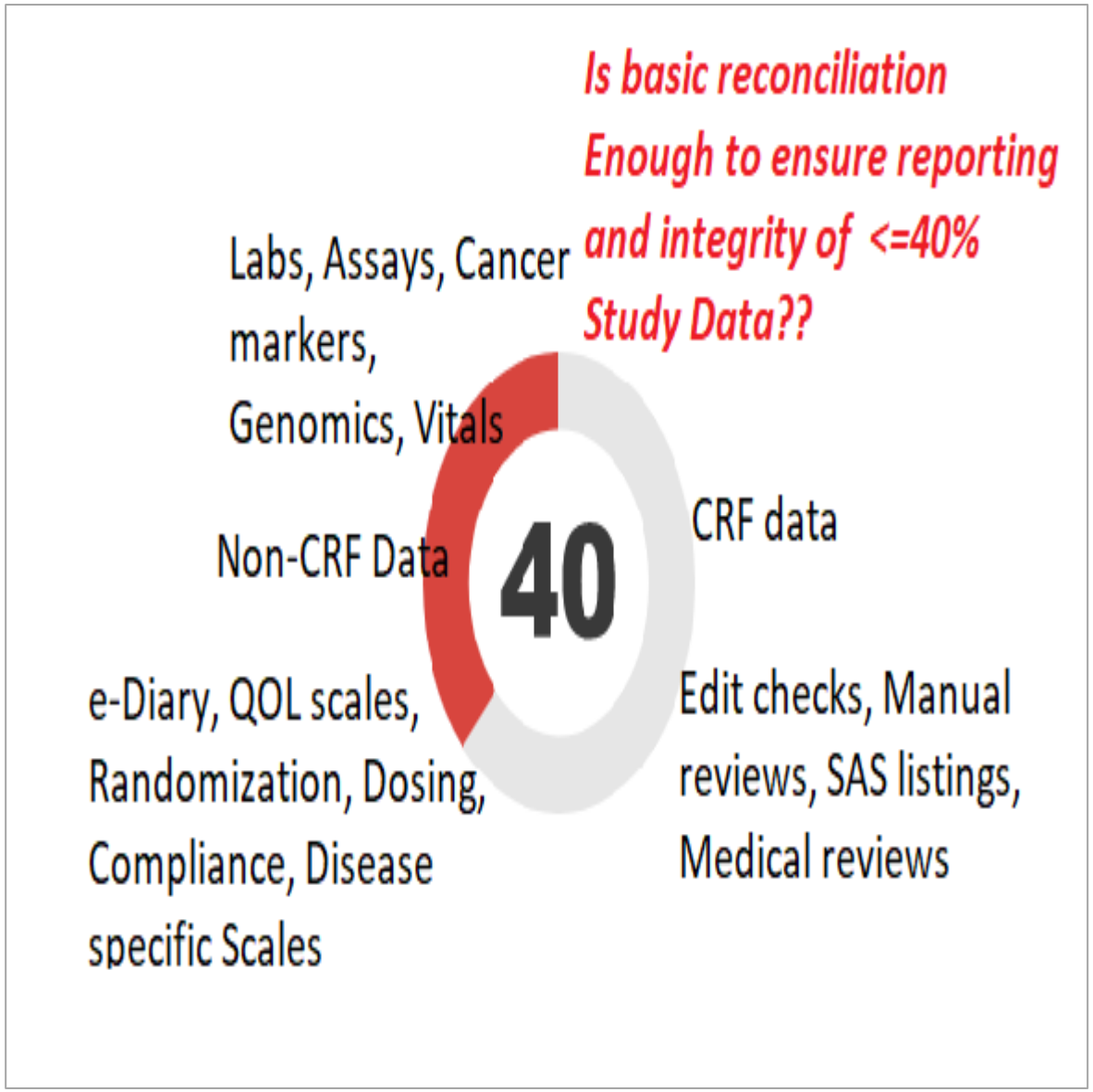


Prior to project milestone or Lock/Freeze, resolve/agree to matches/mismatches and confirm task completion

Era of Collaboration not Data Point Reconciliation



Get involved on Day ONE!



Proactive collaborations and communications:

Phase II Oncology Trial: System Demo and simple observation shared with Imaging vendor.
> $25000 worth costs saved at project start up

Automation, technical limitations:

Large Phase III Trial and Curious case of Duplicate ECGs in vendor system.

- ***Trend analysis, predictive analysis/Risk Management***

> 800 queries in EDC avoided/improved compliance.
>$75000 billing for client avoided despite effort put in corrective actions by DM.

Communication and Collaboration

Missing Samples : Why DM Vs Vendor Counts never Match

Use Vendor sophisticated systems and reports for better tracking a break up of Missing Samples of What's in Vs What's in logistics Vs What is pending

Action Taken to track these missing samples and documentation of vendor and CRO alike!

Are sites sending contradictory updates/changes? Query trends, ignoring feedbacks, Any improvements noted

"The Time is Right according to Me", said the Site and the vendor:

An unusual case of *ECG/Vitals time of collection being exact one hour different in CRF and vendor records*.

Analysis of Who? What? How?
And
What can we do?

Questions to right stakeholders gave us the answer!

Cost and Quality Impacts !

Missing Samples/Lost Samples

Sample Management Costs:
Sample Kit, Tracking, Reporting
Shipping/logistics (<=40% of Cost), Re-Tests, Additional Tests, Training Costs

If not identified at right time can result in >10% increase to project budget in phase III and > 5-10% cost rise in Phase II trial via cost of review, tracking, re-sampling or additional testing due to repeat errors

Human/System Errors

How the error occurred, who is culprit, habitual offender? Timely Corrective Actions by defining stakeholders and follow up reporting

Trend/Predictive Analysis combination reduces query rates to sites from Vendors and DMs alike by 10-15%. Remember every query created, processed is $ charge to Client by every stakeholder.

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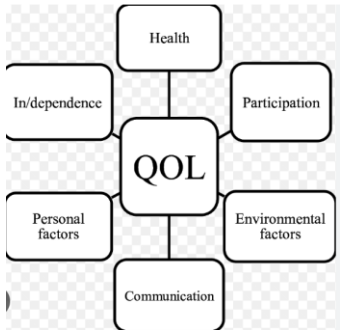
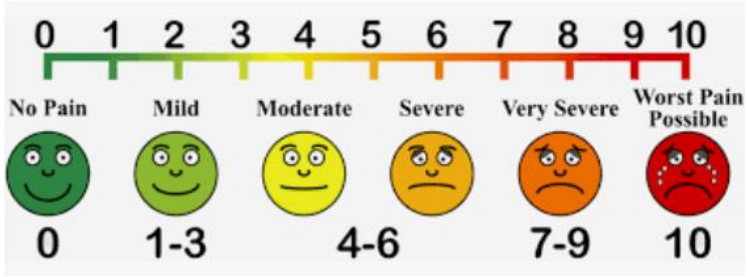
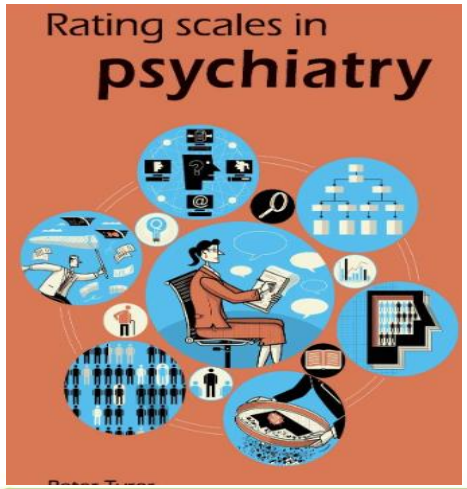
But its Patient reported! – e-Diary Reporting

Is it just Patient reported Outcome or Primary Endpoint
or
Treatment Decisions
Or
Critical decision supporting Data in the Trial?







Can question be skipped?

Types of flags
Prompts

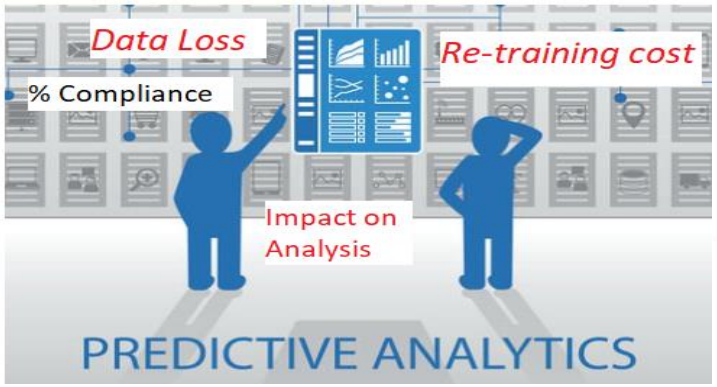
Flags for sites?

Insturctions Vs ease of completion

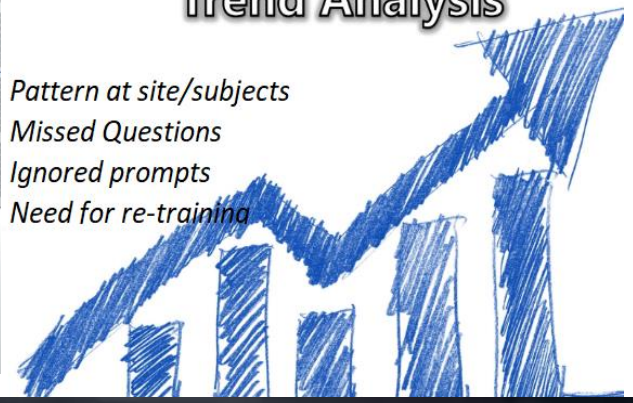
If missed to complete what happens?

Timely corrections to instructions/re-training of sites and patients/Removal of tech glitches

RISK MANAGEMENT



Trend Analysis



Pattern at site/subjects
Missed Questions
Ignored prompts
Need for re-training

The Hidden Goal - PD reporting

Timely Trend Anlysis

5 to 10% reduction in Minor deviations on MIssing/re-tests/Site training, Sampling Handling Training deviations in Phase II and Phase III trials

Improved compliance, reduced missed assessments

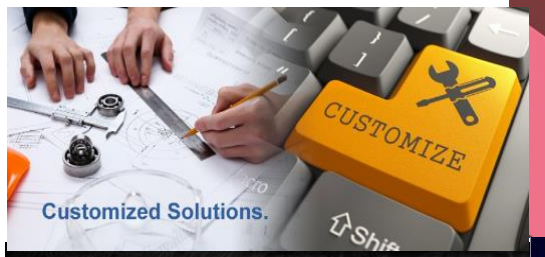
Collaboration: Big Picture Analysis

Budget impacts and trial decisions for Mid Size biotech and Pharma

Prolonging of Project Timelines, associated cost of work and Quality drive future Business decisions and planning for Clients

>50% reduction in repeat business when scope/costs rise due delays and change orders

Favorable Outcomes with Logical, Simple, Replicable process and perspective changes



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