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

Director – Global Project Management, Bangalore

Praveen is a Senior Leader with a proven track record of leading multifunctional teams internationally in the CRO and healthcare industries for the past 18 years. As a solutions partner, he works with internal stakeholders at all levels in a multinational organization in identifying and executing improvement opportunities.

In his current role he is the Director and Head of Global Project management team in India. In this role, he holds responsibility of managing a team of 400 individuals who work on tasks leading to site initiation, sample management, creation of investigator manuals, alerts management, lab programming outputs and kit production.

Praveen has presented in India and global conferences over the past 11 years as a speaker, chair and a debate panelist.

Sr. Clinical Data Management Scientist

Ankita works as a Clinical data manager in Accenture with 9 years of industry experience. She has worked in all phases of clinical trials from DM perspective, she is the key contributor since the inception of trial till the Database Lock.

Her job involves forecasting and foreseeing the right challenges, DM resources for trial, setting up of databases along with data cleaning and database locks.

She is an active member of DM journey where she contributes to mindset change for Data Managers, training new associates, as well as looks for new possibilities in technology to improve to the Data Management services.

Global Data Management Lead – Data Manager, AstraZeneca, Bangalore.

Prateek is a Global data management lead working with AstraZeneca. In the past, he has been associated with various reputed organisations contributing to end-to-end CDM activities from Set-up, Conduct and close-out. He has worked in various therapeutic areas like Oncology, Cardiometabolic, Renal, Metabolism, Auto-immune diseases etc in versatile roles. With a profound 12 plus years of hands-on experience in leading Studies, Teams and Programs, he is currently leading global DM activities as a Sponsor.

He is a certified Medidata Rave Study Builder. He is passionate about CDM and an avid learner. He envisions to be proficient in complete technical aspects associated with CDM which enables him to deliver robust solutions.

Global Data Management Lead- Data Manager, AstraZeneca, Bangalore

Sandhya Raghu is Global data management lead associated with AstraZeneca. She carries an immense experience in CDM for 16 plus years and has gained great learnings by working in different TA's, varied eDC platforms and on different phases of clinical trials. She has worked with some of the prestigious organizations previously and has been good mentor. She aspires to have broad spectrum learning in CDM and has been recognized with several awards in different companies for good project management skills for end-to-end activities in CDM.
She is an inquisitive learner, solution oriented and tries to apply her skillsets in all her tasks.

Principal Clinical Data Scientist-
Caidya, India

Shawli is experienced clinical data management professional working in the Clinical data management division for past 17 years. Her majority of experience and expertise lies in leading Oncology trials.

She has been working as project lead and oversight for Large Phase II/III clinical trials and FSP studies. The exposure at Top Pharma to mid-size CRO DM division in her career has led her to develop an approach of look for simple, logical and replicable solutions via Operational excellence using available tools and technologies for process optimization, innovation or Automation.

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

Disclaimer

The views, analysis, commentary expressed herein are those of the presenter using the information at our disposal to draw conclusions and provide insights; they do not necessarily reflect the views of any organization.

Any resemblance to anyone is purely coincidental.

Third Party Vendor Data Management- Collaboration Strategies
Topics to cover

What is Lab Data Management?

Challenges

Solutions

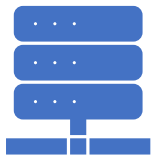
Case Studies

Third Party Vendor Data Management- Collaboration Strategies Introduction

Lab Data Management

Process of collecting, organizing, and analyzing data

Challenges and Solutions



Multiple Vendors, Multiple Data Storage

Vendor Segmentation

Data/ Sample Collection

Data Analytics, Data insights through Predictive analytics

Delay in receipt

Collaboration, Issue logs

Errors arising due to poor quality of data during data transfer and merger

KPI, One digital Platform, Trainings

Third Party Vendor Data Management- Collaboration Strategies Introduction

Predictive Analytics

Extract information from Clinical Trials datasets, trends- resulting better data insights

Detect AE's by analyzing real world evidence

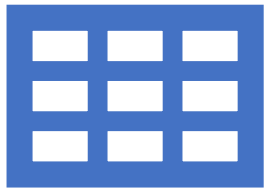
Predict Medication side effects

Study Progress

Effective Vendor Collaboration

Vendor Performance Management

Helps organizations to mitigate risks and drive value driven outcomes.



A centralized data repository can be created to track sample status.

List of KPI's to be shared at the time of signing the contract

Case Study 1- Effective Collaboration

Challenges

- Milestone- Safety data analysis
- Lab Data to be analyzed
- PK, PD Samples missing in vendor database
- Unable to reconcile vendor data affecting timelines
- No communication between sites and lab

Case Study 1- Effective Collaboration Cntd…

Solutions

Identify the issue

Samples not shipped by site

Sample details not uploaded in Lab database

Frequent meetings with CRA and Lab

Agreed Action items and Action owners

Obtain requisition number from sites and track samples

Case Study 1- Effective Collaboration Cntd..

Outcome

- 100% of samples status was known
- 80% of Samples were shipped and were made available in Vendor database
- Samples present in Vendor- details were uploaded in database
- 20% samples were considered as Lost in transit
- Safety Analysis achieved

Case Study 2- Vendor Segmentation/ Metrics/ KPI

Challenges

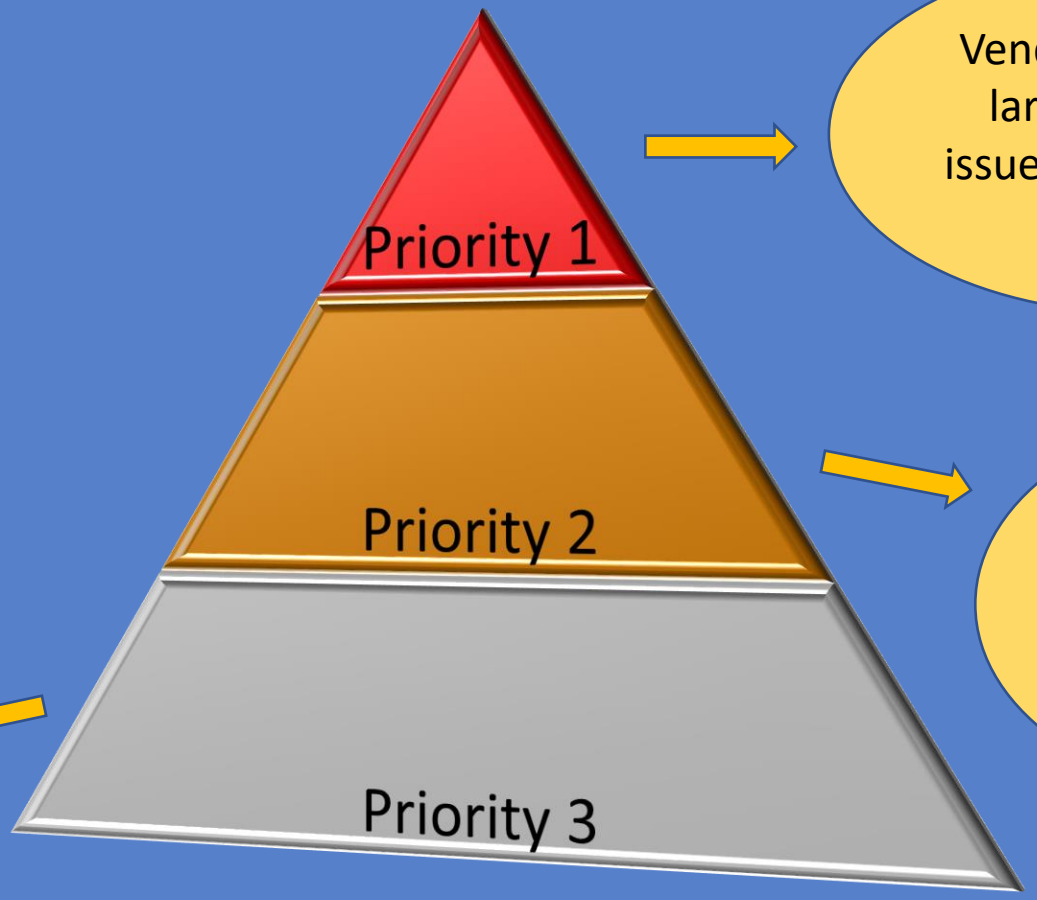
- Multiple Vendors and multiple datasets
- Inconsistent performance by Vendor
- No mechanism to track status

Case Study 2- Vendor Segmentation/ Metrics/ KPI Cntd…

Solutions

Vendor segmentation

Segregated samples based on maximum issues



Vendor which have large number of issues. High risk e.g.: PK/ PD

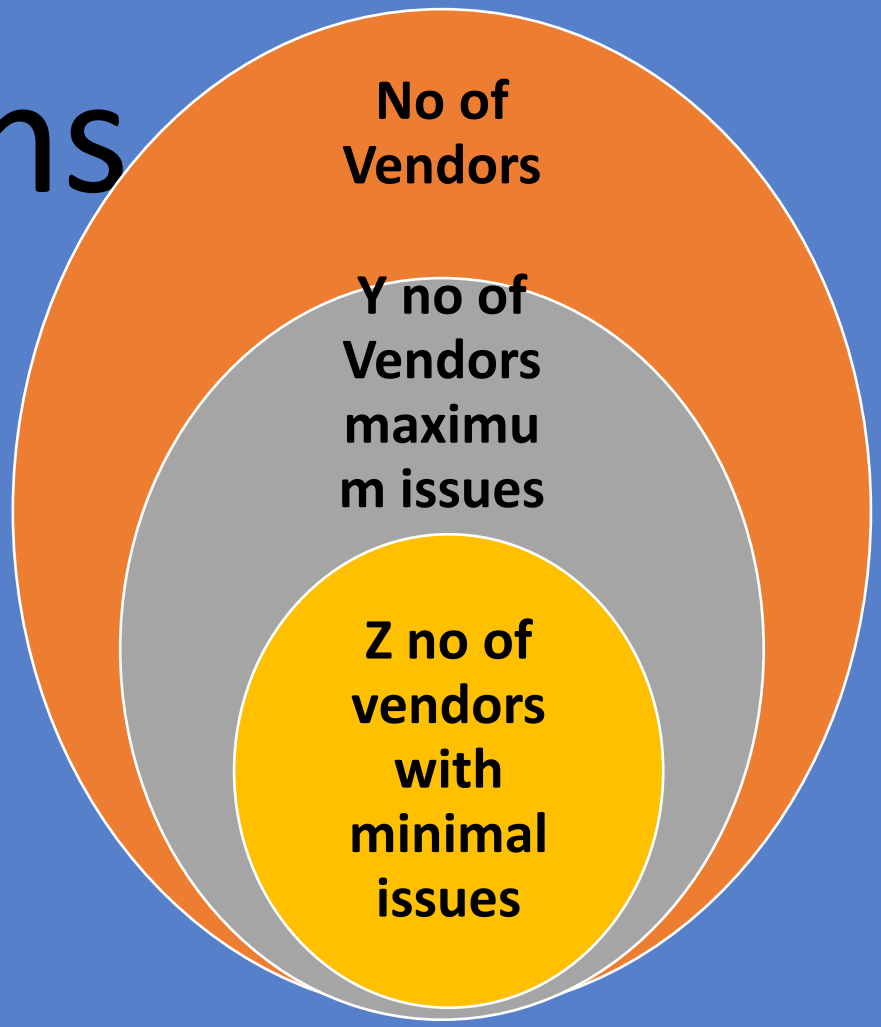
Vendor which have minimal number of issues. Moderate risk e.g.: ePRO

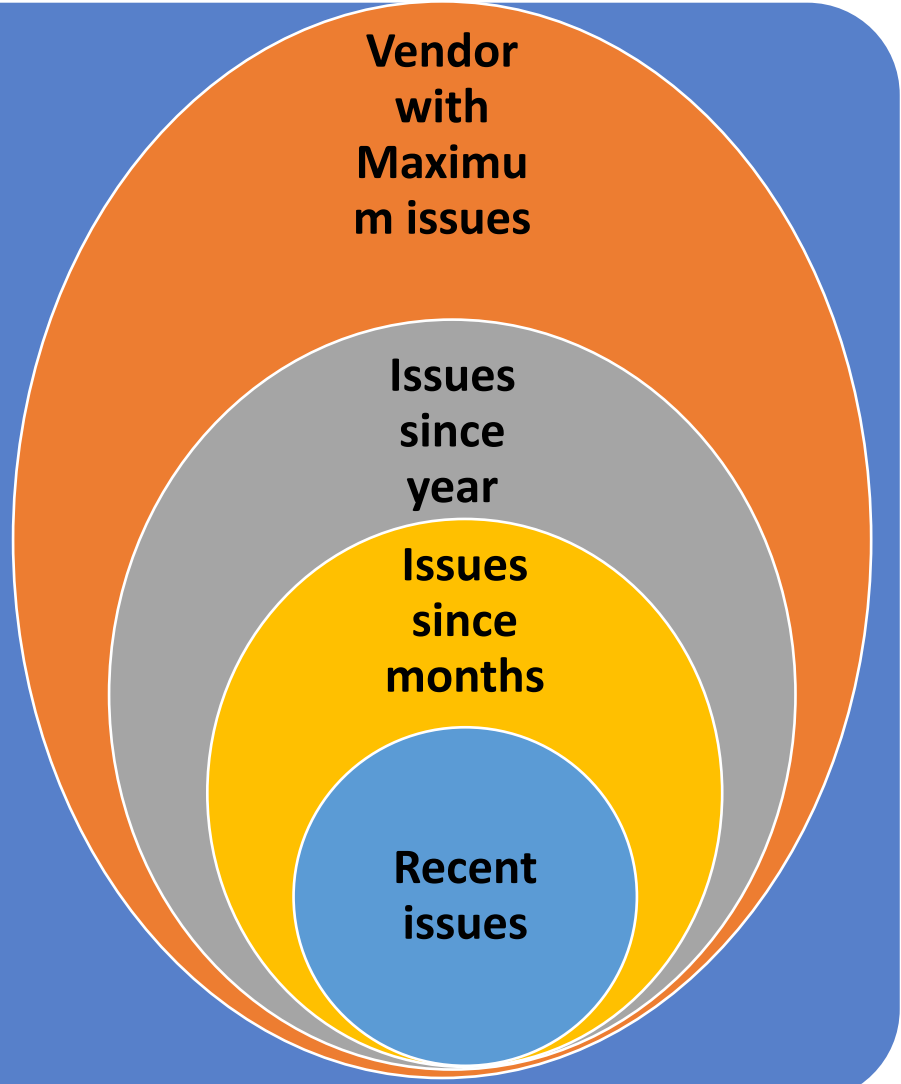
Vendor which have low number of issues. Low/ No risk e.g.: PgX

Case Study 2- Vendor Segmentation/ Metrics/ KPI Cntd…

Solutions

Preparing Metrics, KPI, sharing on weekly basis





Case Study 2- Vendor Segmentation/ Metrics/ KPI Cntd…

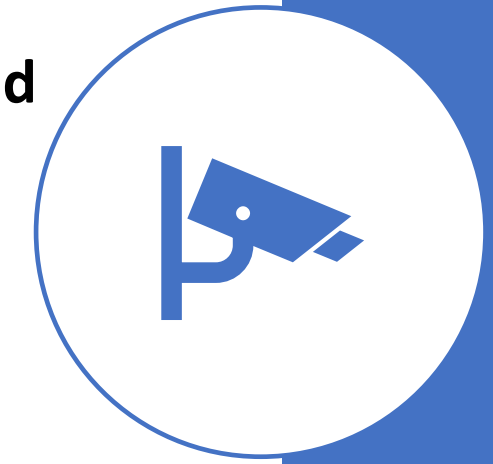
Outcome

- Performance improvement was Tracked
- Decision made possible to select and continue with which vendor
- Benefitted other trials

Summary

Key points to remember are:

- **Results from TPV are crucial as used for Subject Screening, trend analysis, Monitor routine safety.**
- **Provide vendor status via KPI**
- **Highlight issues in timely manner before they stack**
- **To mitigate vendor challenges, communicate, collaborate on regular intervals.**



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

Presenters

Prateek Sharma
Global DML AstraZeneca

Sandhya Raghu
Global DML AstraZeneca

Index

Collaboration

Advantages & Challenges

Case study

Opportunities

Advantages & Challenges of Collaboration

Advantages

- Involvement of different stakeholders leads to different ideas to handle a problem.
- Exchange of knowledge helps to fill the gap in process
- Early risk detection
- Creates Opportunities
- Robust planning and fixes

Challenges

Lack of Cross functional collaboration

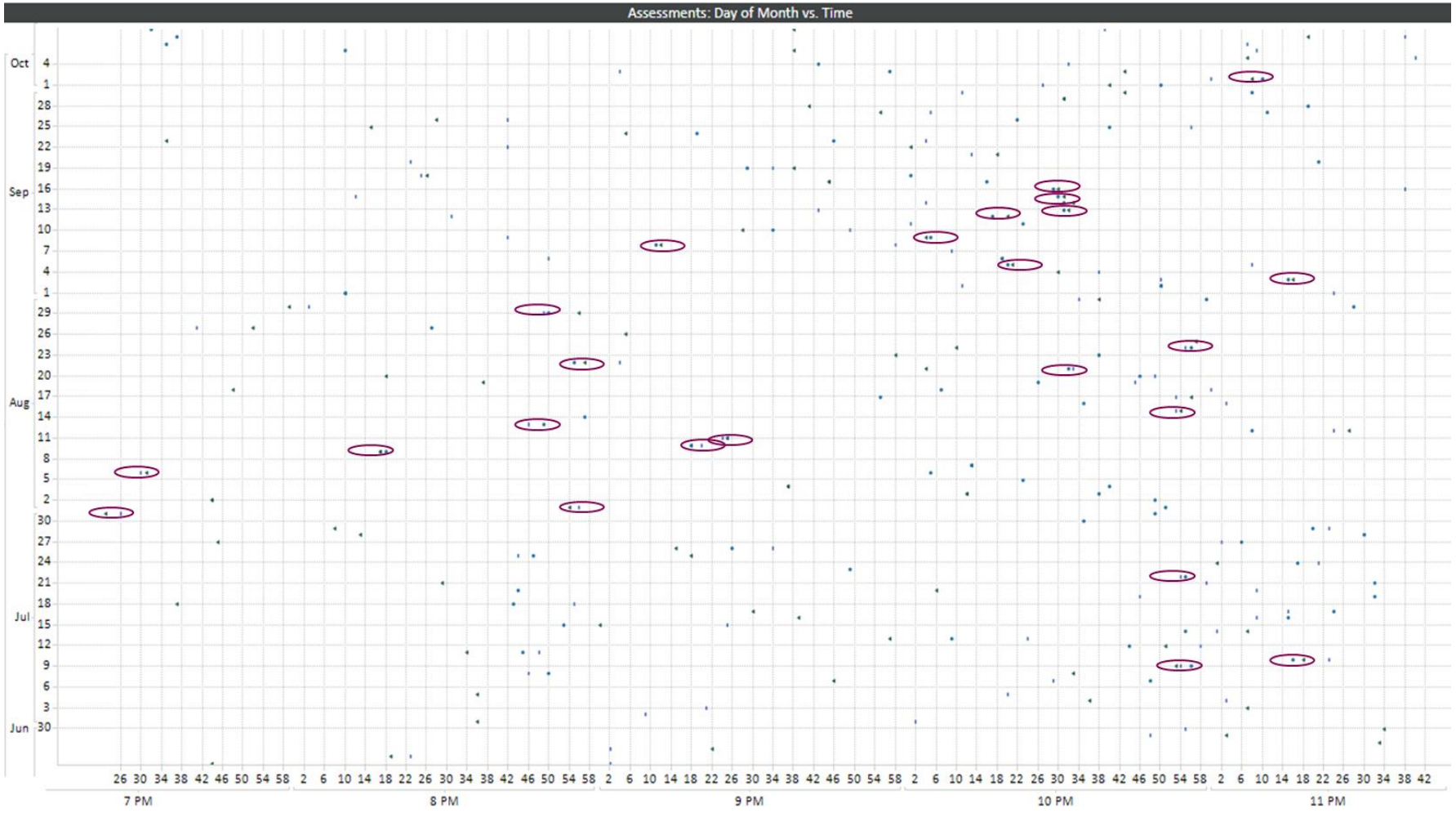
- Type of data being dynamic and differs on type of samples.
- Poor quality of DTA first version
- Lack of clarity on the impact of data flowing downstream.
- Missing samples at the time of DBL.
- Identifying issues after the merging of unblinded data.

Case Study


WORLD TRAFFIC
Total Orders
13,678
Total Sales
11,892
Total Profit
$6,789
Analysis

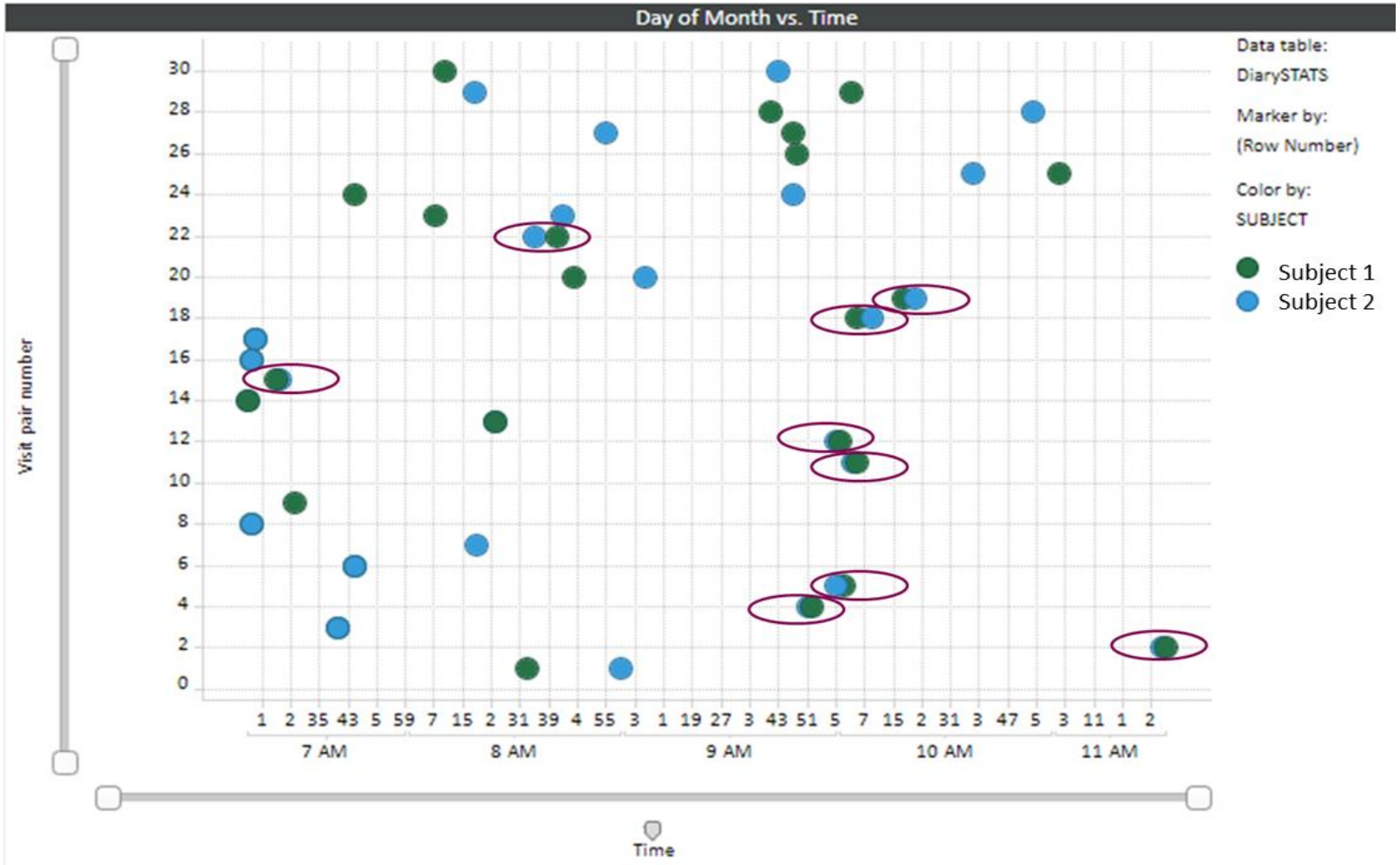
ePRO completion patterns – a tale of two studies

Time analysis of ePRO data – overlapping patterns observation



ePRO completion patterns – Study A

Time pattern of single site for study A



ePRO completion patterns – Study B

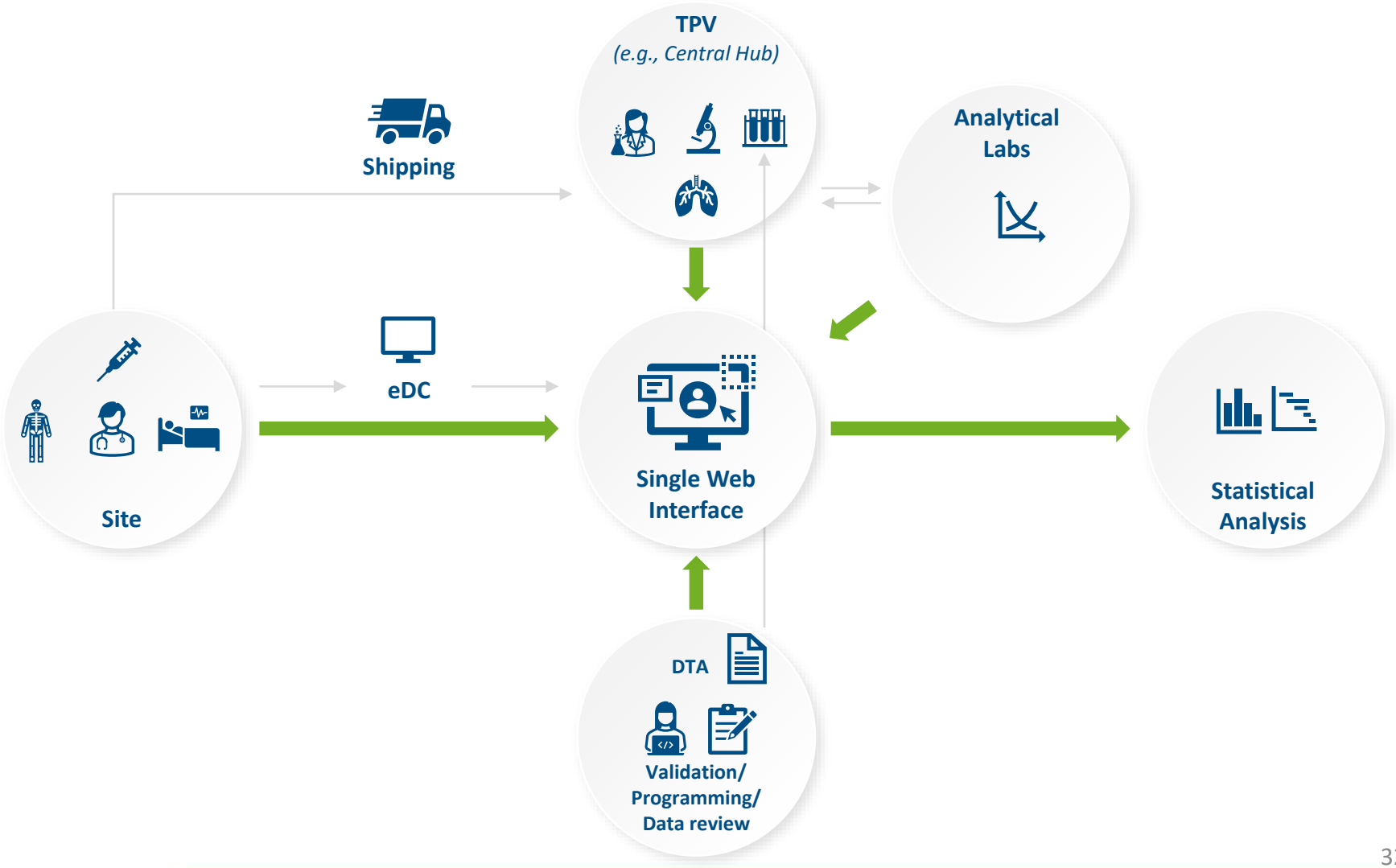
Time pattern of single site for study B

Opportunities

Creating a Single Web Interface tool which can get all the stakeholders onboarded together, right from DTA creation, through the finalizing of the data at DBL.

#1

Based on concepts of HP-ALM® tool



Few considerations for Single Web Interface

- Authentications and authorizations.
- Since it is single entry point, we must ensure system is up and running.
- It should be scalable and should be able to handle more requests.
- Blinding privileges to be considered as applicable.

User Management review to periodically taken care by respective stakeholders.

Structuring variables in DTA templates as per SDTM standards at the start to minimize the data processing for SDTM conversions.

#2

Efforts of SDTM processing on raw data will be reduced.

- Raw data is more standard in nature
- Turnaround time reduced
- Issues being fixed at early stage

LBORRES

LBORRES (Result or Finding in Original Units) can be converted in their standard values.

LBFLAG

LBFLAG provided by some vendors can be mapped to variable LBNRIND (Reference Range Indicator) per SDTM standards.

LBORRESU

LBORRESU (Original Units) can be converted in standard units.

LBORNRLO

LBORNRHI

Similarly Variables like EPOCH, VISITNUM, VISIT can be defined directly from TV domain in DTS.

Robust servers to perform metadata checks as soon as the data is received from vendor and let the data flow at next staging area only if it is compliant.

#3

TPV Programmer DM

- Raw data is compliant with spec
- Issues are being flagged directly to vendor

TPV data sent by vendor + Run Metadata Checks + TPV data is loaded in DM systems → Send error logs (if any) to the Vendor & copy DM.

Performing the pinnacle 21 checks

#4

Programmer Site DM

"Start early, Resolve early"

Over the years it has been observed that Pinnacle 21 checks are performed towards the end of study.

Most of the data issues observed in the output has resulted in updating the source data (i.e., CRF data or Vendor data).

The TAT of the fixing of vendor data is the highest and at the time of DBL most challenging.

30-40% of the Pinnacle checks can be directly checked in the source data before it is converted into the SDTM datasets.

Hence proactively designing these checks at the server level will have a great impact on the data quality.

Predictive analysis to predict the next expected samples and flagging it in advance. Like Visit Calendar and Overdue features as in Rave database

#5

TPV Programmer DM Site

A feature primarily to enable visibility to DM

- Define Time & Event Schedule for TPV data per Protocol within Web Interface.
- Calendar set up for tracking visits and samples.
- Rules to flag alerts on sample collections based on ICD, visit dates and subject status.
- Alerts for overdue/ missing sample collection, late sample collection, incomplete or incorrect sample details.

Robust validations prior to final DBL for unblind data which is critical and time bound

#6

TPV Programmer
Statistician
Site DM

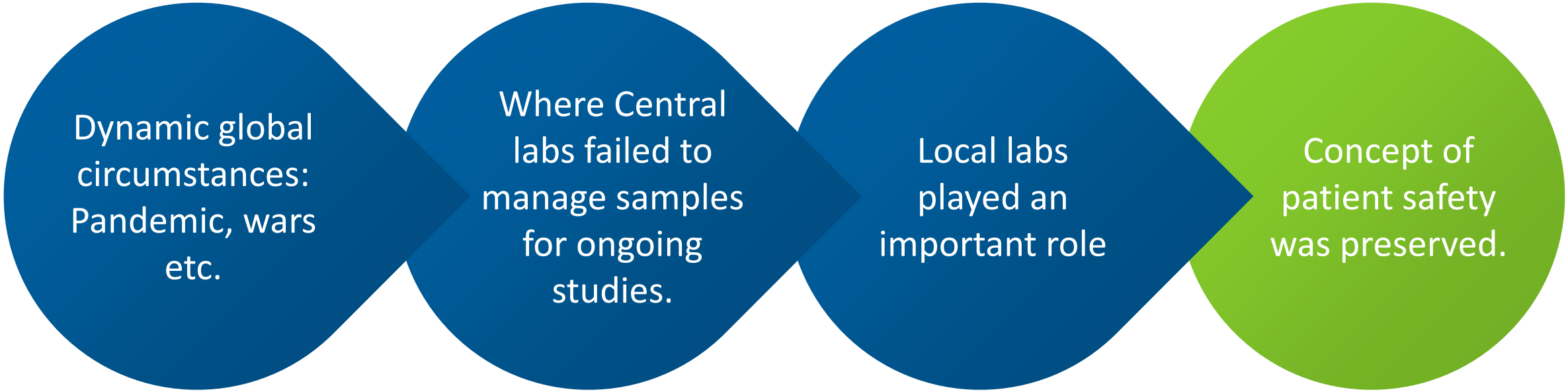
Collaborating with programmers, data reviewers and TPV support POC plays a major step.

Dummy results to be transferred to DM prior to DBL to ensure successful merging of datasets.

During conduct, a thorough structural/ header validation are performed.

Post DBL data includes- PK, Pharmacogenetics, Exploratory.

Can Local Labs be ignored?



Takeaways

- **Effective collaboration is a must**
- **Collaboration driven through technology, can have positive impact**
- **With increasing demand having drug faster in market, TAT for TPV data management to be reduced efficiently.**
- **Tackling issues before DBL can reduce the risk of delayed submission.**
- **Bridging gaps between central lab and local labs for smooth transition of data.**

Affiliations

Prateek Sharma

Data Manangement CDI, Development Operations, R&D, AstraZeneca, Bengaluru, India

Sandhya Raghu

Data Management CDI, Development Operations, R&D, AstraZeneca, Bengaluru, India

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

Presenters

Prateek Sharma
Global DML AstraZeneca

Sandhya Raghu
Global DML AstraZeneca

Index

Collaboration

Advantages & Challenges

Case study

Opportunities

Advantages & Challenges of Collaboration

Advantages

- Involvement of different stakeholders leads to different ideas to handle a problem.
- Exchange of knowledge helps to fill the gap in process
- Early risk detection
- Creates Opportunities
- Robust planning and fixes

Challenges

Lack of Cross functional collaboration

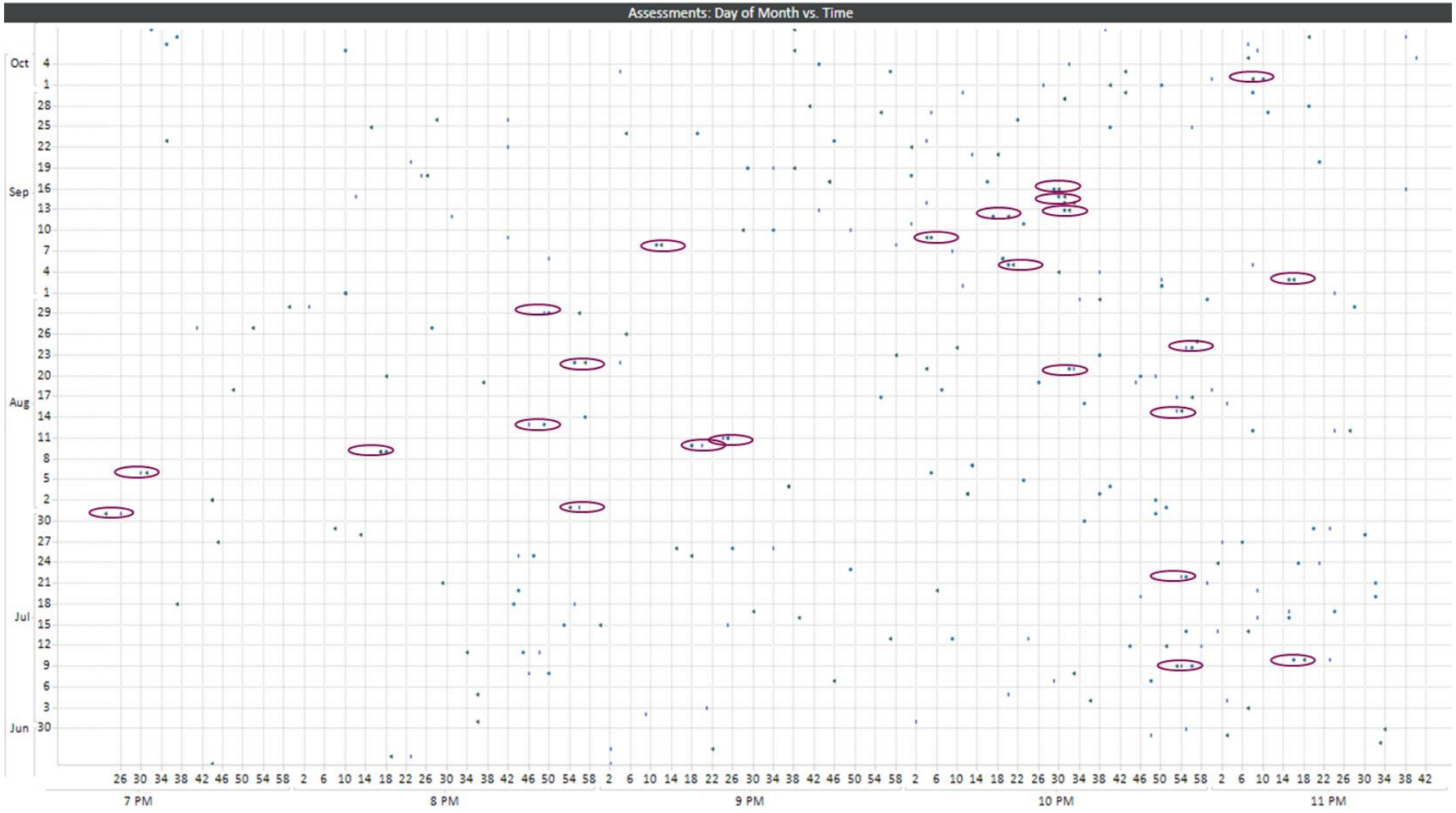
- Type of data being dynamic and differs on type of samples.
- Poor quality of DTA first version
- Lack of clarity on the impact of data flowing downstream.
- Missing samples at the time of DBL.
- Identifying issues after the merging of unblinded data.

Case Study


WORLD TRAFFIC
Total Orders
13,678
Total Sales
11,892
Total Profit
$6,789
Analysis

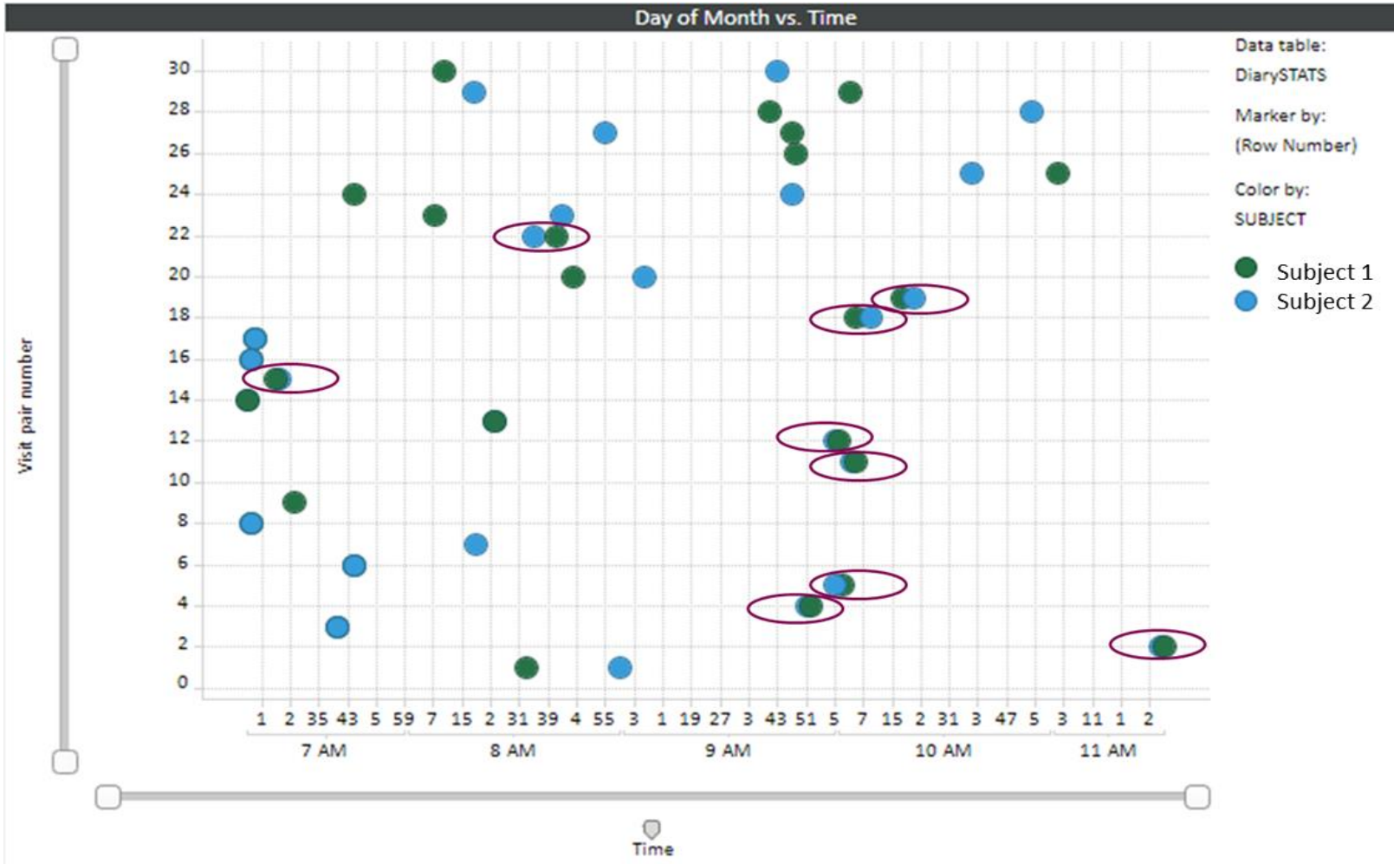
ePRO completion patterns – a tale of two studies

Time analysis of ePRO data – overlapping patterns observation



ePRO completion patterns – Study A

Time pattern of single site for study A



ePRO completion patterns – Study B

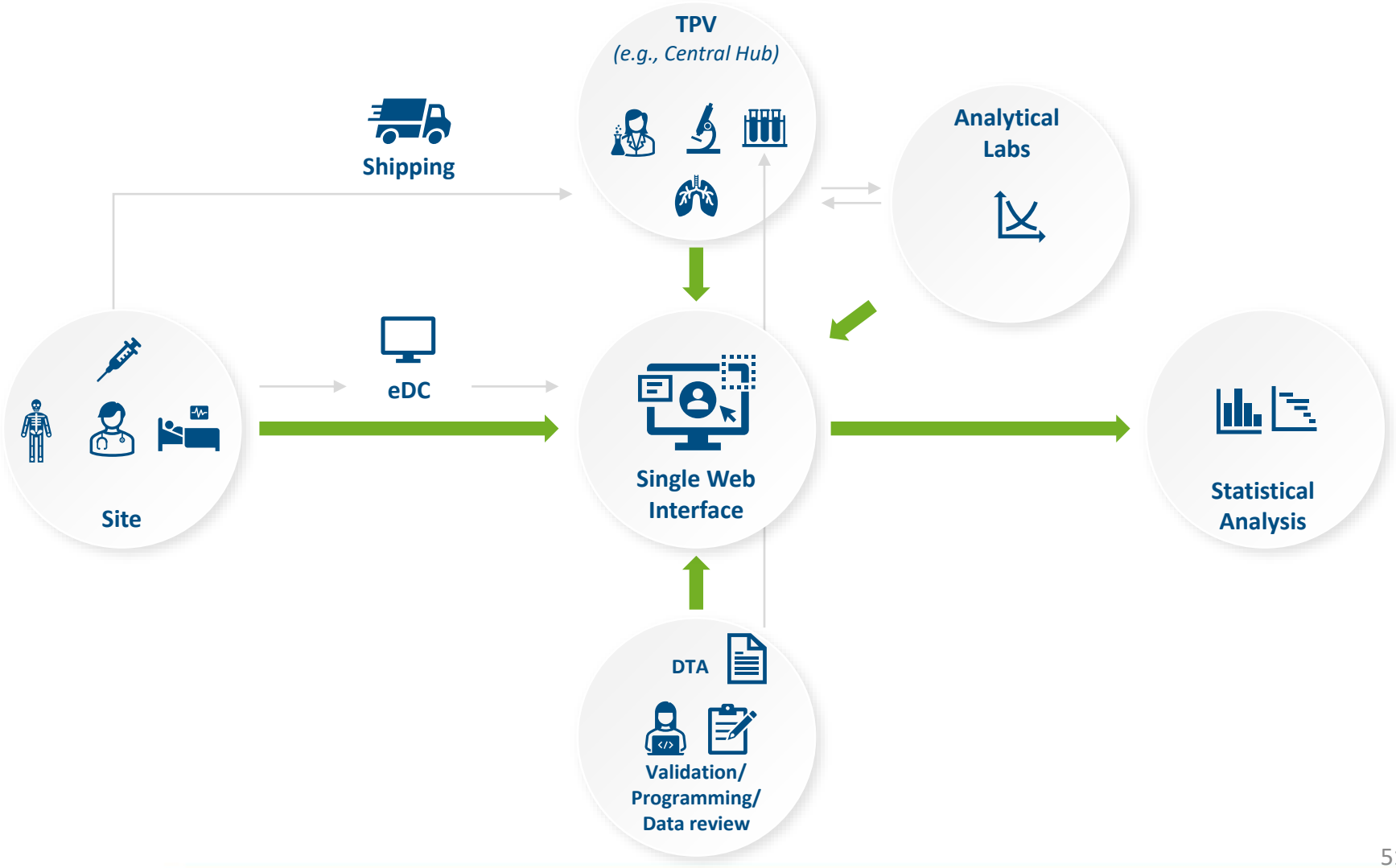
Time pattern of single site for study B

Opportunities

Creating a Single Web Interface tool which can get all the stakeholders onboarded together, right from DTA creation, through the finalizing of the data at DBL.

#1

Based on concepts of HP-ALM® tool



Few considerations for Single Web Interface

- Authentications and authorizations.
- Since it is single entry point, we must ensure system is up and running.
- It should be scalable and should be able to handle more requests.
- Blinding privileges to be considered as applicable.

User Management review to periodically taken care by respective stakeholders.

Structuring variables in DTA templates as per SDTM standards at the start to minimize the data processing for SDTM conversions.

#2

Efforts of SDTM processing on raw data will be reduced.

- Raw data is more standard in nature
- Turnaround time reduced
- Issues being fixed at early stage

LBORRES

LBORRES (Result or Finding in Original Units) can be converted in their standard values.

LBFLAG

LBFLAG provided by some vendors can be mapped to variable LBNRIND (Reference Range Indicator) per SDTM standards.

LBORRESU

LBORRESU (Original Units) can be converted in standard units.

LBORNRLO

LBORNRHI

Similarly Variables like EPOCH, VISITNUM, VISIT can be defined directly from TV domain in DTS.

Robust servers to perform metadata checks as soon as the data is received from vendor and let the data flow at next staging area only if it is compliant.

#3

TPV Programmer DM

- Raw data is compliant with spec
- Issues are being flagged directly to vendor

TPV data sent by vendor + Run Metadata Checks + TPV data is loaded in DM systems → Send error logs (if any) to the Vendor & copy DM.

Performing the pinnacle 21 checks

#4

Programmer Site DM

"Start early, Resolve early"

Over the years it has been observed that Pinnacle 21 checks are performed towards the end of study.

Most of the data issues observed in the output has resulted in updating the source data (i.e., CRF data or Vendor data).

The TAT of the fixing of vendor data is the highest and at the time of DBL most challenging.

30-40% of the Pinnacle checks can be directly checked in the source data before it is converted into the SDTM datasets.

Hence proactively designing these checks at the server level will have a great impact on the data quality.

Predictive analysis to predict the next expected samples and flagging it in advance. Like Visit Calendar and Overdue features as in Rave database

#5

TPV Programmer DM Site

A feature primarily to enable visibility to DM

- Define Time & Event Schedule for TPV data per Protocol within Web Interface.
- Calendar set up for tracking visits and samples.
- Rules to flag alerts on sample collections based on ICD, visit dates and subject status.
- Alerts for overdue/ missing sample collection, late sample collection, incomplete or incorrect sample details.

Robust validations prior to final DBL for unblind data which is critical and time bound

#6

TPV Programmer
Statistician
Site DM

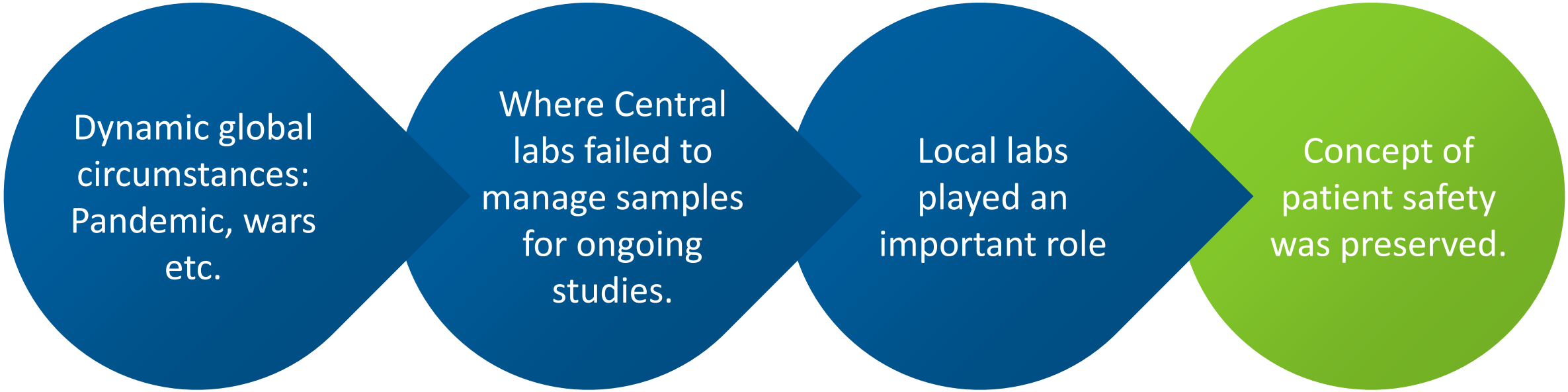
Collaborating with programmers, data reviewers and TPV support POC plays a major step.

Dummy results to be transferred to DM prior to DBL to ensure successful merging of datasets.

During conduct, a thorough structural/ header validation are performed.

Post DBL data includes- PK, Pharmacogenetics, Exploratory.

Can Local Labs be ignored?



Takeaways

- **Effective collaboration is a must**
- **Collaboration driven through technology, can have positive impact**
- **With increasing demand having drug faster in market, TAT for TPV data management to be reduced efficiently.**
- **Tackling issues before DBL can reduce the risk of delayed submission.**
- **Bridging gaps between central lab and local labs for smooth transition of data.**

Affiliations

Prateek Sharma

Data Manangement CDI, Development Operations, R&D, AstraZeneca, Bengaluru, India

Sandhya Raghu

Data Management CDI, Development Operations, R&D, AstraZeneca, Bengaluru, India

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

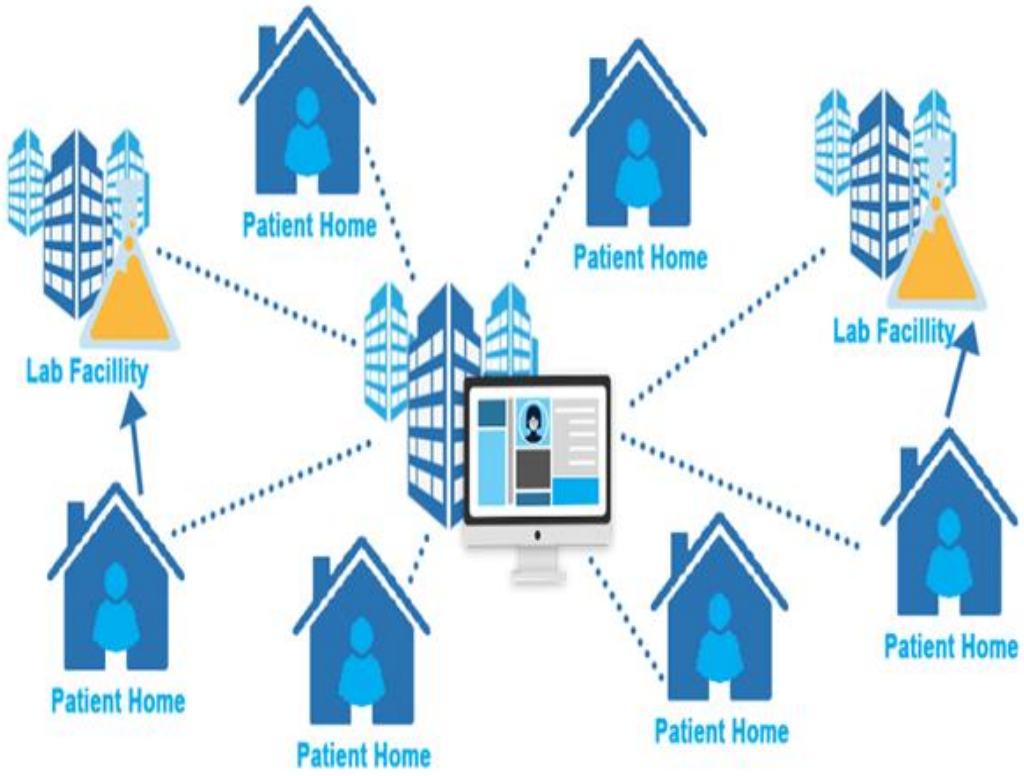
Data Manager's Role Beyond Data Point Reconciliation

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.

Pictorial depictions are taken off internet browsers for knowledge sharing purposes only and no copyright infringements intended.

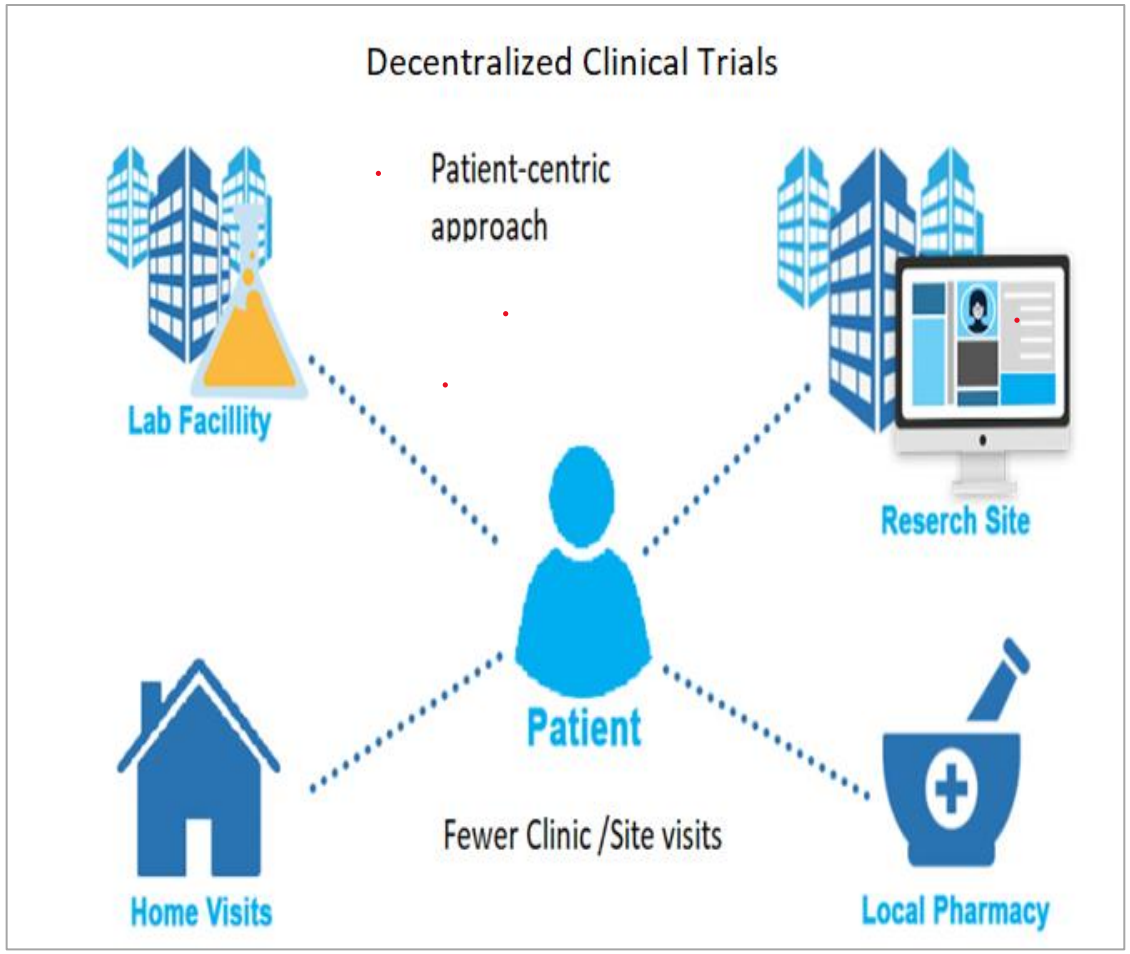
Traditional Clinical Trials and Third-Party Data

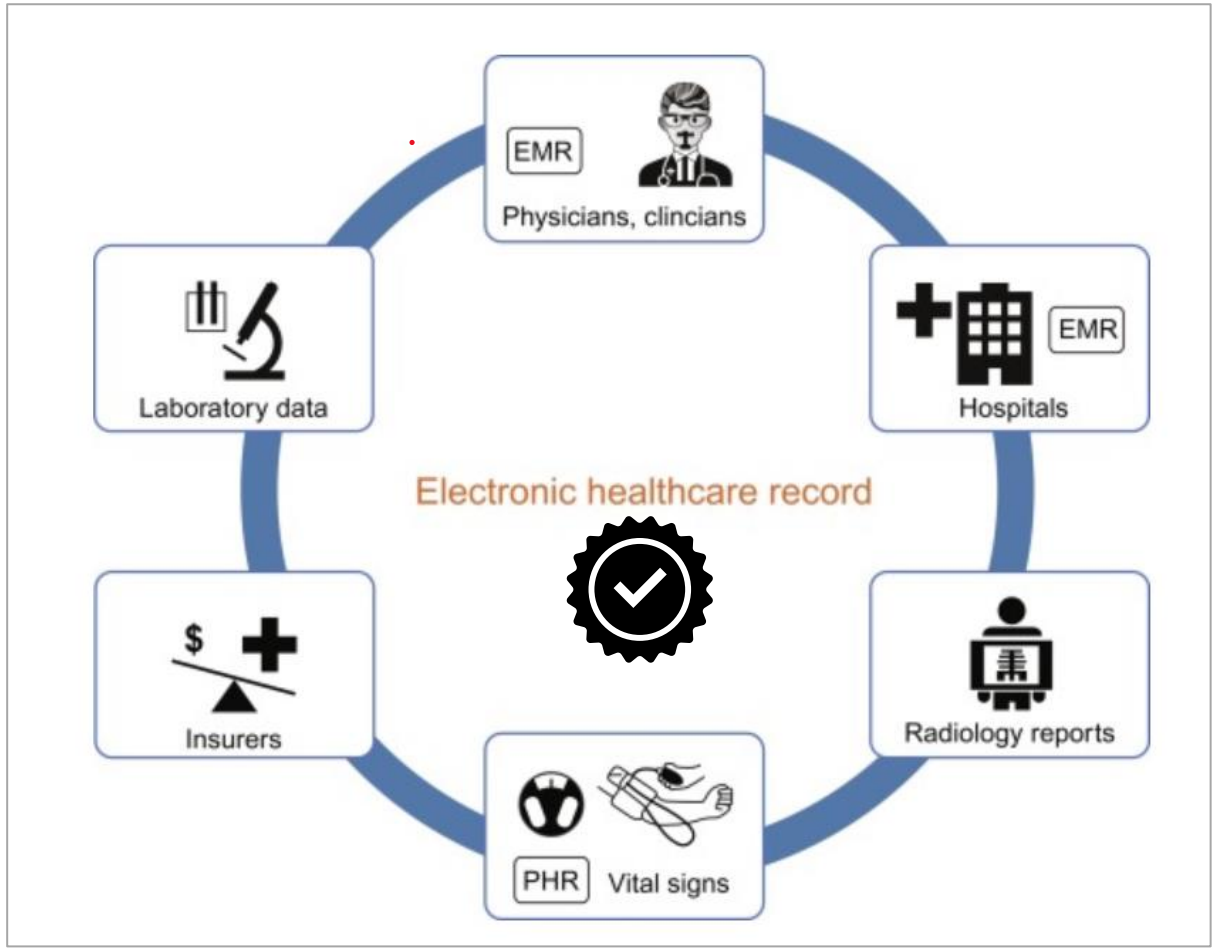
Traditional apporach: Hospital visits for Dosing, check ups, tests and follow ups despite introduction of EDC tools for data collection



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

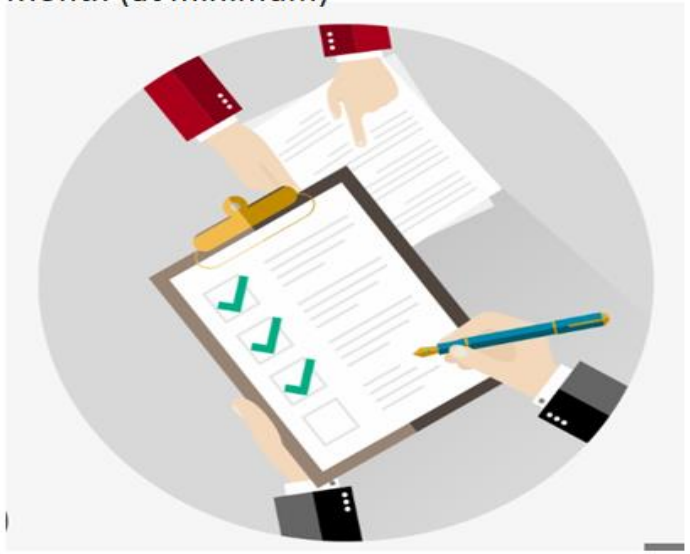
All parties accessing same data, audio, video access, consults

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

Is Data Manager's Participation Enough?

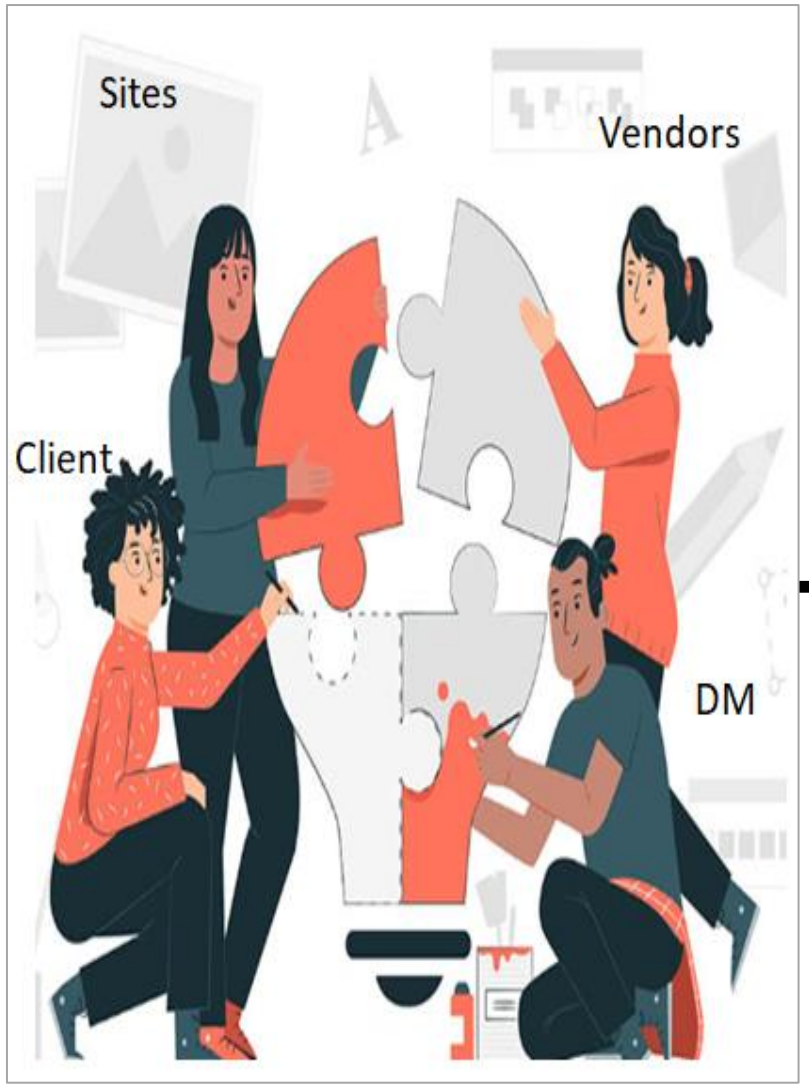
File format, Minimum identifiable data points to match records in EDC Vs vendor file

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

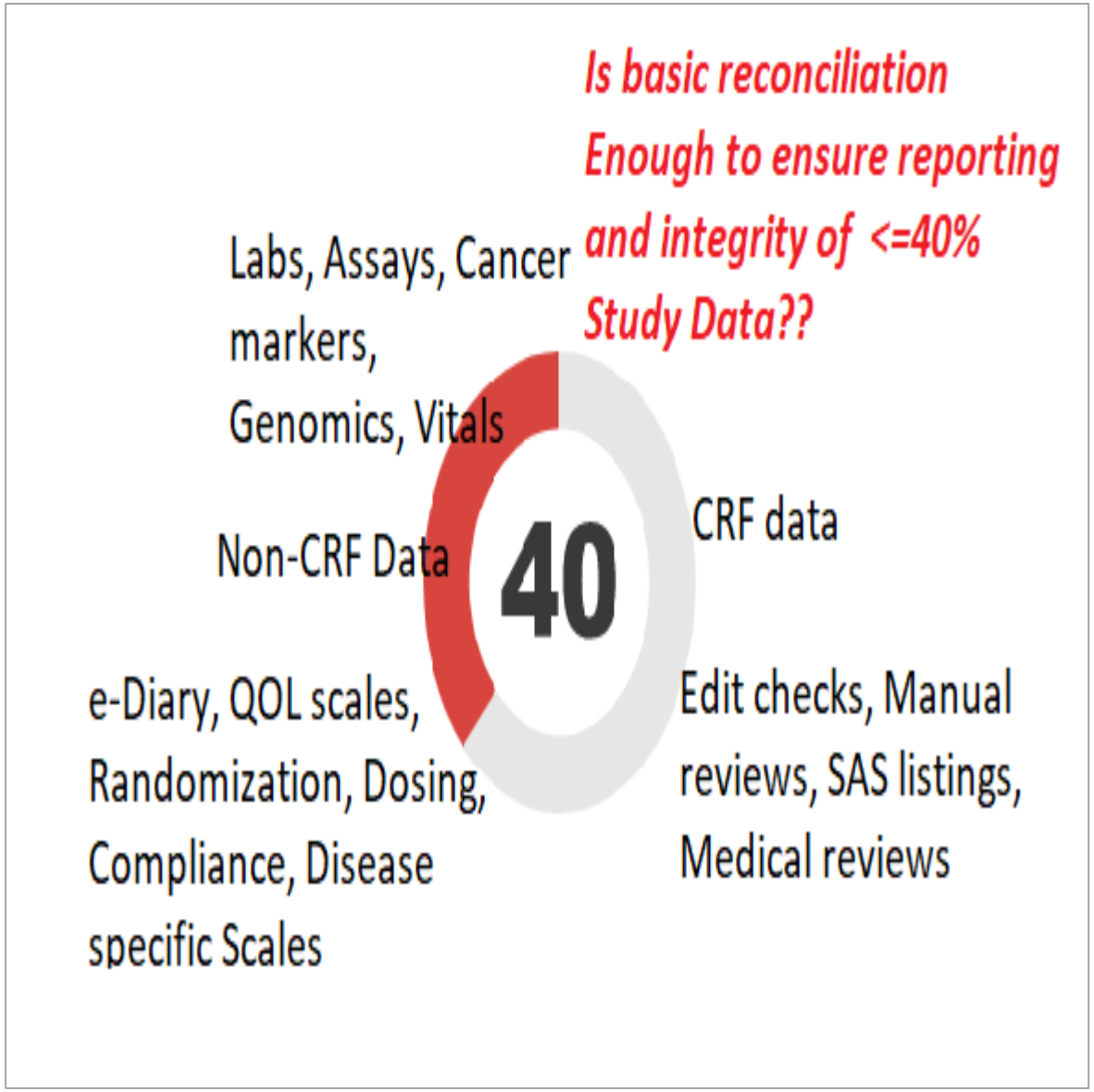


Prior to project milestone or Lock/Freeze, resolve/agree to matches/mismatches and confirm task completion

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

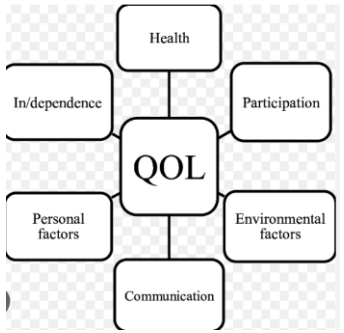
How the error occurred, who is culprit, habitual offender? Timely Corrective Actions by defining stakeholders and follow up reporting

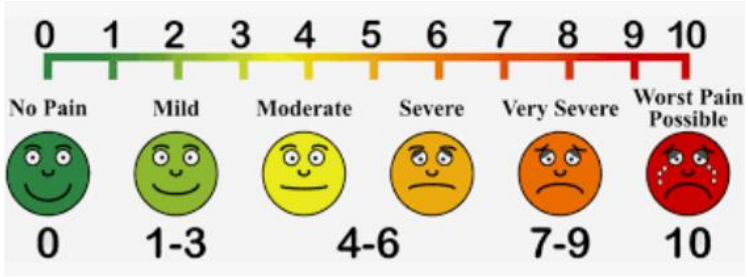
Trend/Predictive Analysis combination reduces query rates to sites from Vendors and DMs alike by 10-15%. Remember every query created, processed is $ charge to Client by every stakeholder.

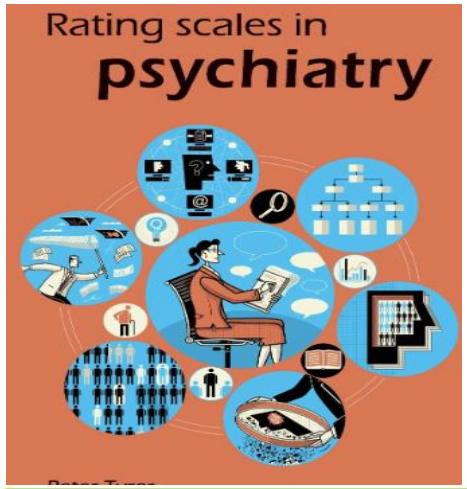
SCDM Live India conference
2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

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?







eDiary

Can question be skipped?

Types of flags Prompts

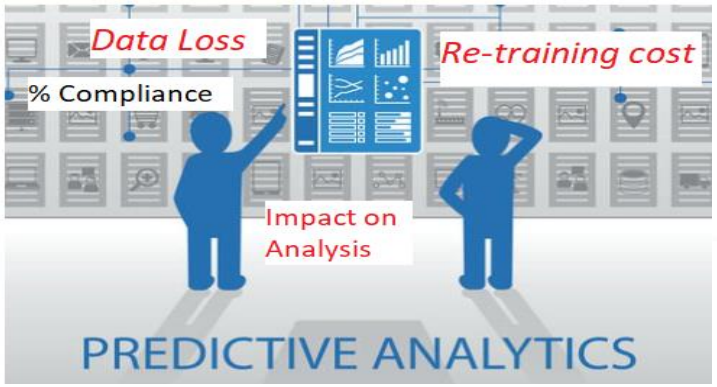
Flags for sites?

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

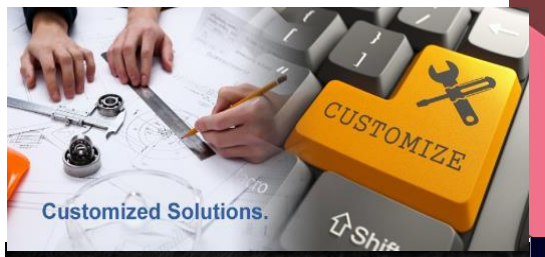
Collaboration: Big Picture Analysis

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



Contact Information

- Official Email: Shawli.das@caidya.com
- Personal Email: shawli.das@gmail.com
- LinkedIn Profile: **Shawli Das**

Q & A