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

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THIRD PARTY VENDOR DATA MANAGEMENT- COLLABORATION STRATEGIES

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Collaboration
Advantage
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Q&A

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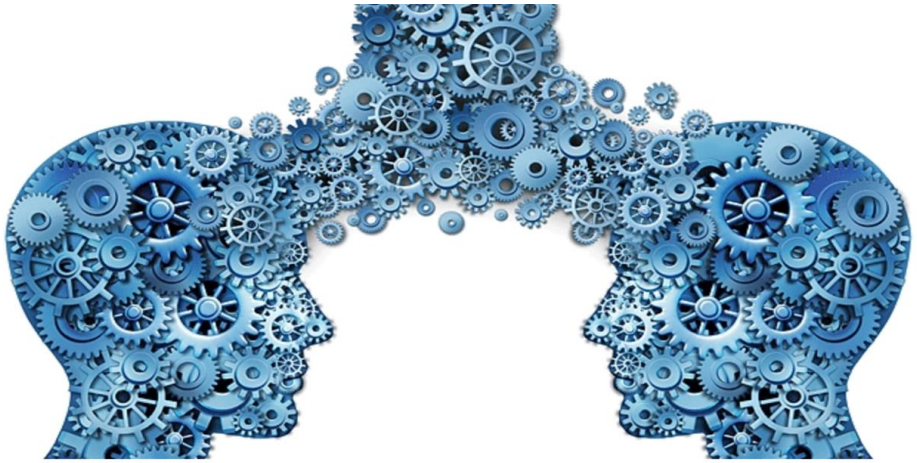


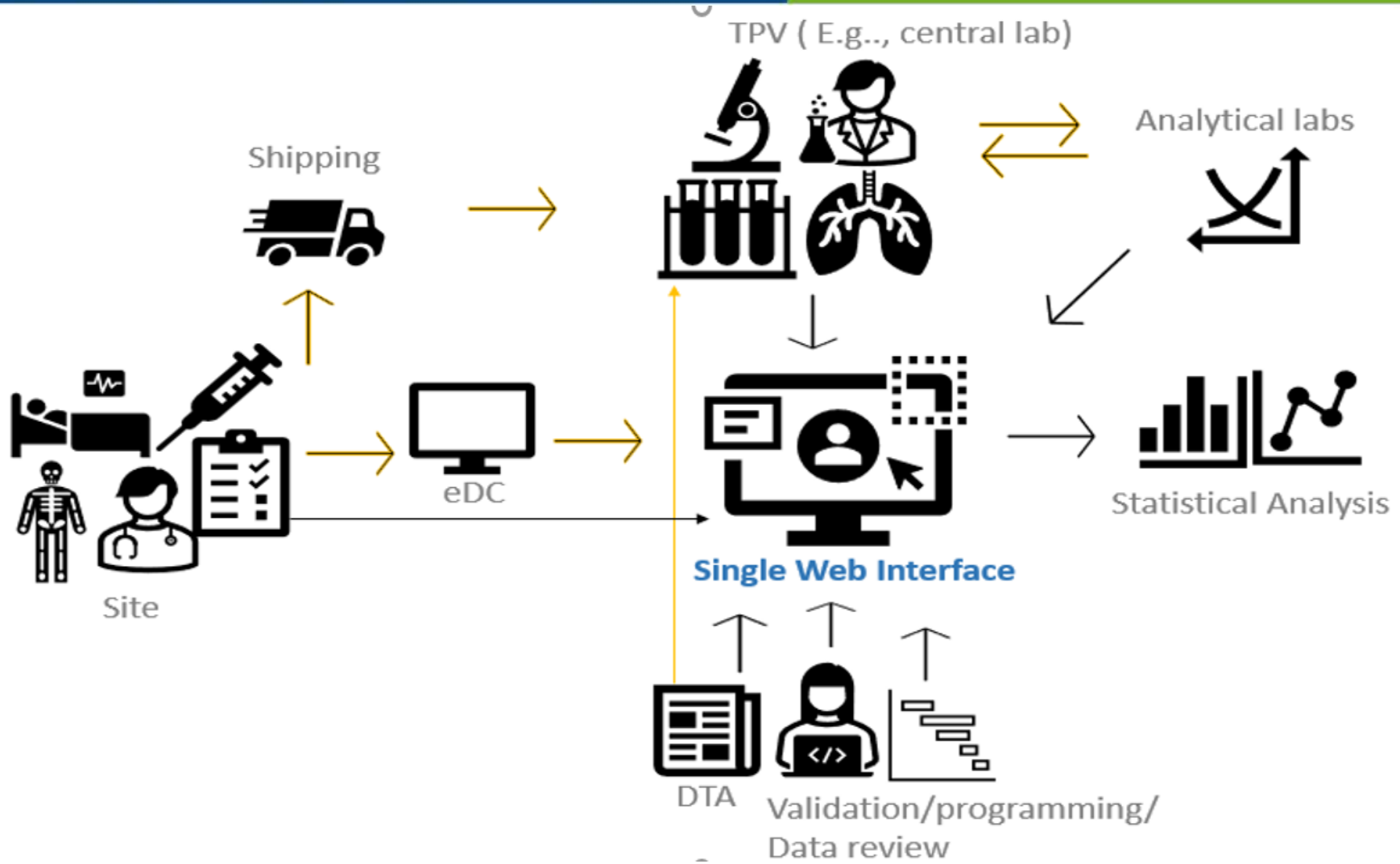
A working practice whereby individuals work together for a common purpose to achieve business benefit.

COLLABORATION

ADVANTAGE OF COLLOBORATION

COLLOBORATION CHALLENGES

OPPURTUNITIES

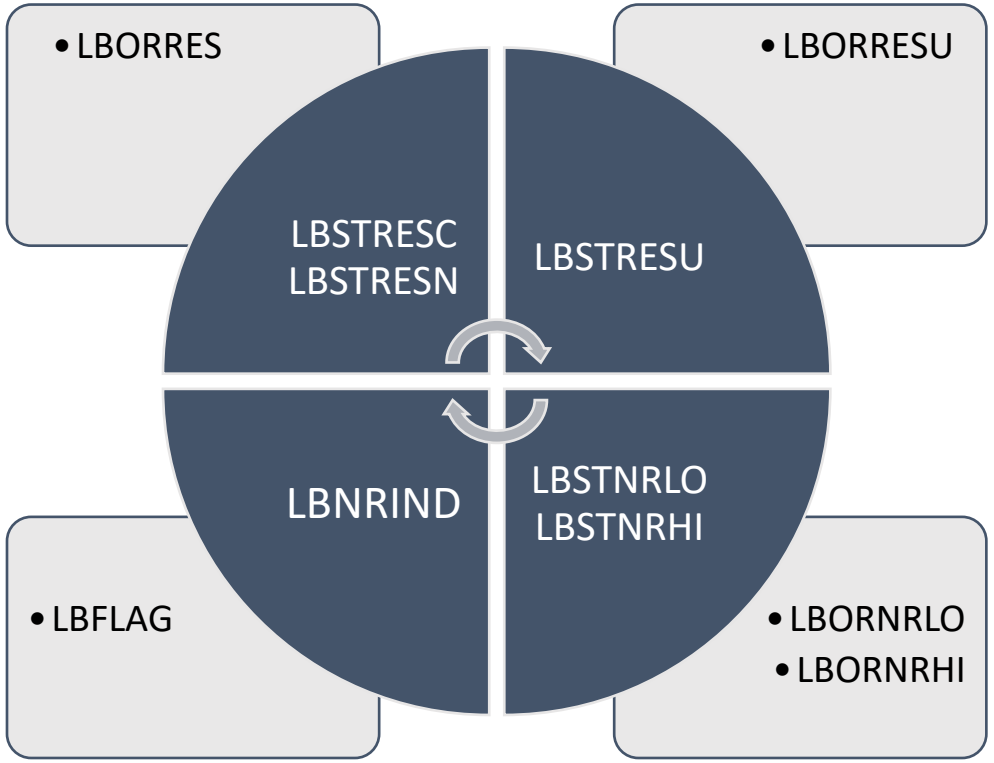


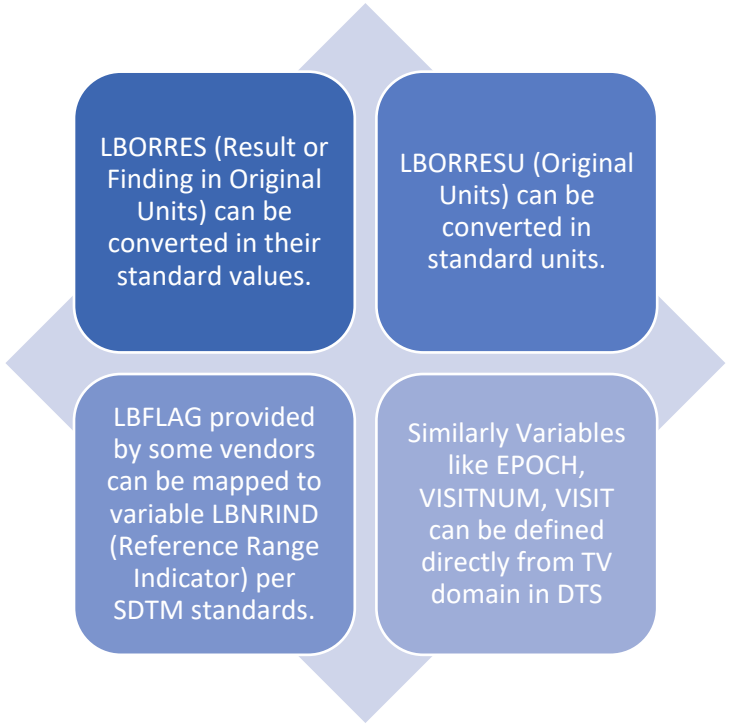
Creating a Single Web Interface tool which can get all the stakeholders onboarded together, right from DTA creation, through the finalizing of the data at DBL.

- 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.

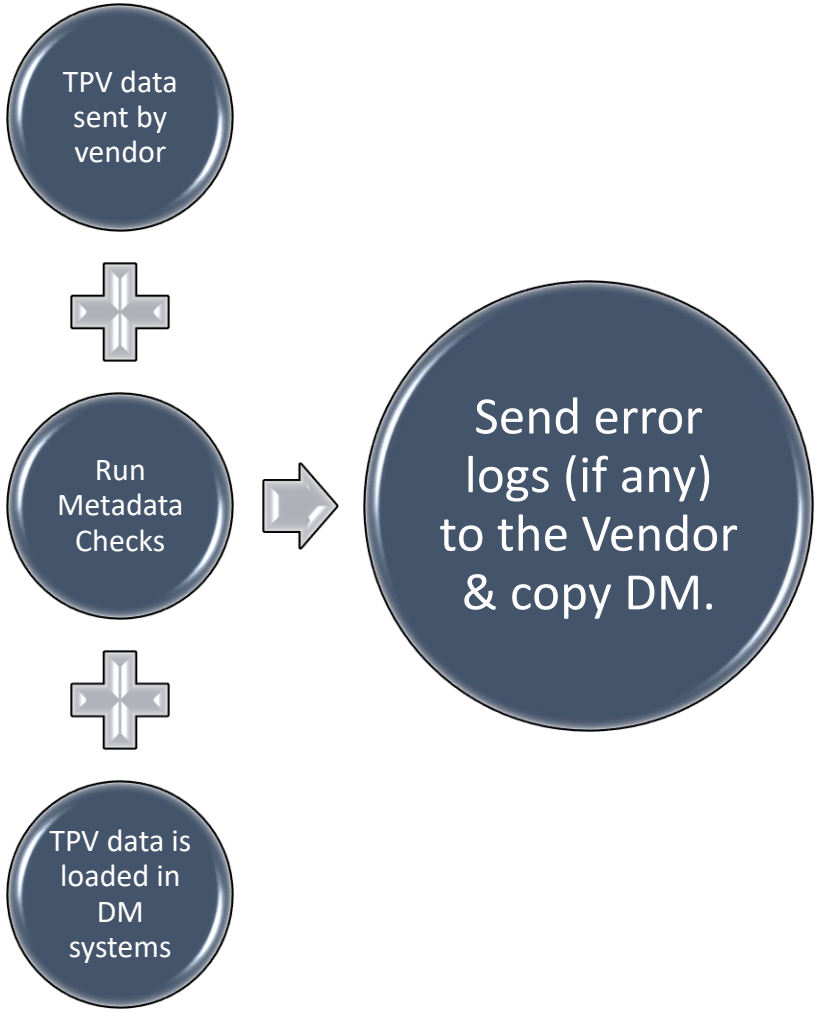
Few considerations for Single Web Interface

In SDTMIG the domain specification uses variables which can be directly defined in the DTA as a result of which these variables can be directly mapped to SDTM datasets without any processing post the data is received.



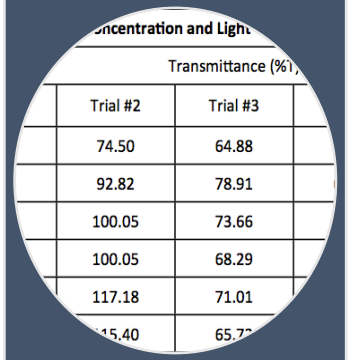


Structuring variables in DTA templates as per SDTM standards at the start to minimize the data processing for SDTM conversions.



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.

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.

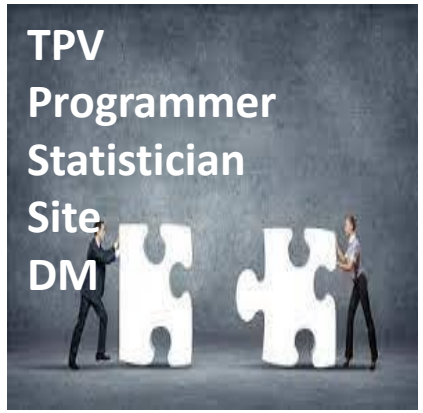
30-40% of the Pinnacle checks can be directly checked in the source data before it is converted into the SDTM datasets.

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

Performing the pinnacle 21 checks at the server level to make sure Submission critical errors are caught at the right time.

- 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

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



- Usual data expected post DBL are results for PK, Pharmacogenetics, Exploratory.
- During conduct, we need to ensure structural/ header validation are performed rightly per DTA DM along with programmers.
- Dry run data with dummy results to be transferred to DM prior to DBL to ensure there are no issues encountered post DBL.
- During Dry run check with Bio statistician, programmer about the datasets, as sometimes it involves merging of datasets which may have impact in data.
- Thorough validation in collaboration with programmers, data reviewers for data review and reconciliations with TPV support plays a major step to avoid future complexities.

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

Q&A

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