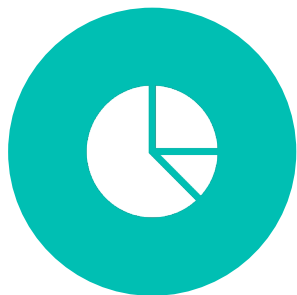


Single Day Event

Programming Support in Licensing Activity – a case study sharing

Johnson & Johnson (China) Investment Ltd.

Agenda



Background



**Challenges
&
Solutions**



Summary

Background



Background

Study Type : An Investigator Initialized Study

Available Information:

- a. Summary report & publications
- b. CRF with limited information collected
- c. Other sources of information in various formats

Expectation:

- a. Collect relevant source information to build the database
- b. Draft analysis plan, create analysis datasets and generate TLGs
- c. Generate comprehensive CSR for business decision

Challenges & Solutions



Challenges & Solutions - Team

– Challenge :

Analysis scope is unclear pending on the availability, format and source of the data

– Solution :

Catalog various sources of data (through cross functional collaboration)

- Summary report & publications: aggregated summary
- E-copy of CRF: I/E criteria, demographics, diagnosis, some baseline labs, dosing, incomplete AEs & ConMeds, etc.
- Excel sheets: PK, dosing, biomarker, some efficacy, etc.
- E-copy of patient medical records (病历)

Get involved in source data review, Continuous learning on what data is available, accessible, reliable and analyzable.



Challenges & Solutions - Team

– Challenge :

Quick turnaround from receiving the source data to analysis reporting

– Solution :

Quick evaluation on what existing system/process can be utilized and what need to be developed or adjusted

- Data exchange, data extraction & convert, database, data entry & checking, analysis data creation, TLGs, etc.

Core functions having the same understanding on the data enables the quick decision making

- Break the routine functional R&R, Core functions work together on all data relevant activities
(integration of medical data review, data management, data analysis and reporting)

Identify the key data points to be collected in database and to be analyzed

Data flow is designed to facilitate analysis (analysis driven)

Programming takes some project management role for data related activities

Everyone be flexible, proactive, responsive, cooperative and innovative



Challenges & Solutions - Team

– Challenge :

Ensure data quality and compliance

– Solution :

Establish the data management and analysis process following GCP principals to ensure data integrity and accuracy

Use Programming check for all the manual data processes

Training on the disease area knowledge and the new processes

Documentation of all the data relevant steps (Including Note To Files)

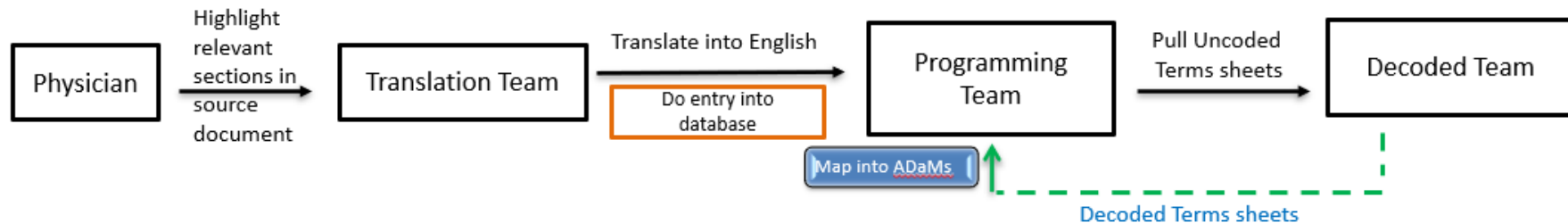
Emphasize on Patients' privacy & data de-identification

– Challenge :

AEs, prior therapies and concomitant therapies collection, translation and coding

– Solution :

Flow Diagram



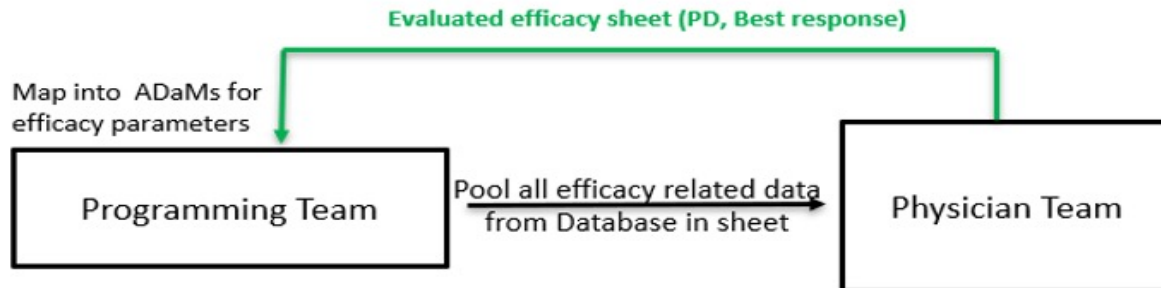
– Challenge :

No efficacy (Response and PD) data

– Solution :

Programming facilitates the efficacy evaluation

Flow Diagram





Challenges & Solutions - Programming

– Challenge :

Data issues & discrepancies between different sources

– Solution :

Develop code to compare 2 times manual data entries

Logical check for critical data by programming code (e.g.: death date)

Cross check different sources when ADaMs are created

Generate listings from ADaM for medical review



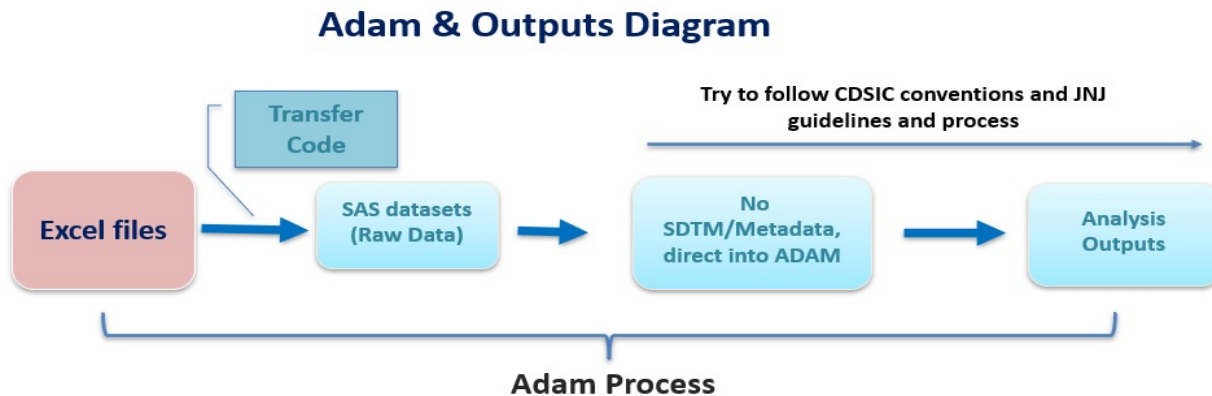
Challenges & Solutions

– Challenge :

Future integration and data exploration

– Solution :

ADaM like analysis datasets that easy to be converted to CDISC compliant



Summary

- ✓ **Review/Check Data from physician/data manager/statistician's position**
- ✓ **Propose solutions to problems rather than seeking solutions from others**
- ✓ **Bring a whole picture to drive data process forward**
(project management, assignment, potential risk prediction, proactively collaboration with functions)
- ✓ **Flexible but not compromise the quality & compliance**

THANK YOU



**The Global Healthcare
Data Science Community**

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