



PP09- Statistical Programming Team Contributions to Registrational Clinical Research Collaborations (rCRC)

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Abstract

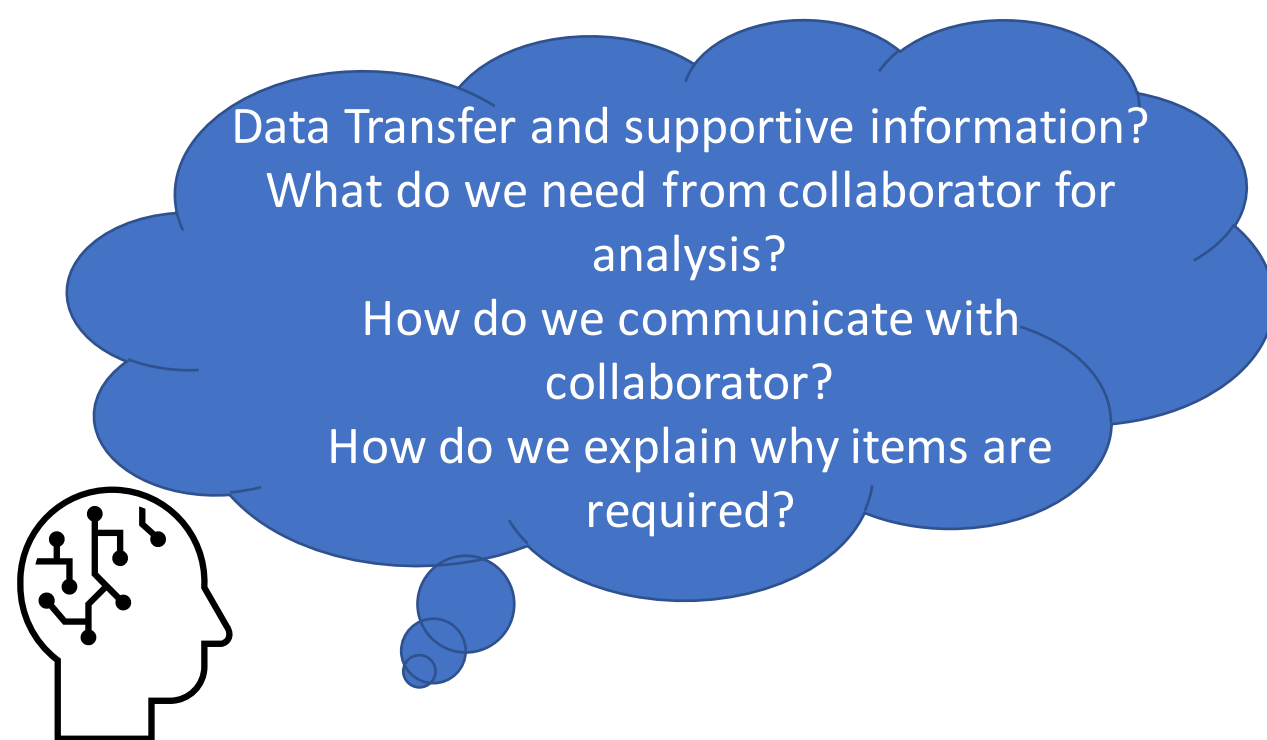
Pfizer has a number of collaborative studies with academic collaborators and their study data are intended to be used for Pfizer regulatory submissions. Statistical programming team has been involved in more than statistical programming activities but engaged with collaborators of the trials to gain alignment of Pfizer submission activities using their data by explaining regulatory requirements and Pfizer processes for the successful regulatory submissions. Number of collaborative discussions and meetings and SMEs input are needed between organizations as interest of data usage and processes are different between pharmaceutical and academic collaborators. Proactively preparing for the technical challenges are critical for the successful submission. The poster is to illustrate the involvement and contribution of the statistical programming team to successful regulatory submissions using CRC collaborator data for Pfizer regulatory submissions.

What is rCRC?

Registrational Clinical Research Collaborations (rCRC) is any clinical research study (Pfizer collaborates with an academic institute and Pfizer is not the regulatory or study sponsor) intended to be used for regulatory submission purpose including primary submission, supplemental submission, label change, post marketing commitment, pediatric submission.

Contract between Pfizer and collaborator

rCRC contracts need to be fit for the purpose of regulatory submission and cross functional SMEs are required to be involved at the early contract development stage. Details of what are required should be specified in the contract.



Regulatory submissions

- Are we clearly sharing our goals?
- Is collaborator clear with our requests?
- It helps to explain regulatory requirement.

Collaborator relationships (cross functional)

Collaborator

Should know...

- Intention of the data usage
- Submission E2E processes and activities
- Future communication and topics
- TEAM

Pharma Company

Should know...

- Collaborator prior experiences
- Capacity/Resourcing
- System/software
- Data collection
- Documentation
- Algorithms
- Data integrity
- TEAM

- Align algorithms and analysis - engage collaborator stats and programming team earlier would be better
- Understanding difficulties and concerns of collaborator and help them to resolve
- Explain submission obligations with HA (e.g. : RRT, Pooled analysis, Labeling updates) and submission requirements and standards (CDISC & P21)
- P21 data issue discussions with collaborator

To support submission... Need Data transfer including:

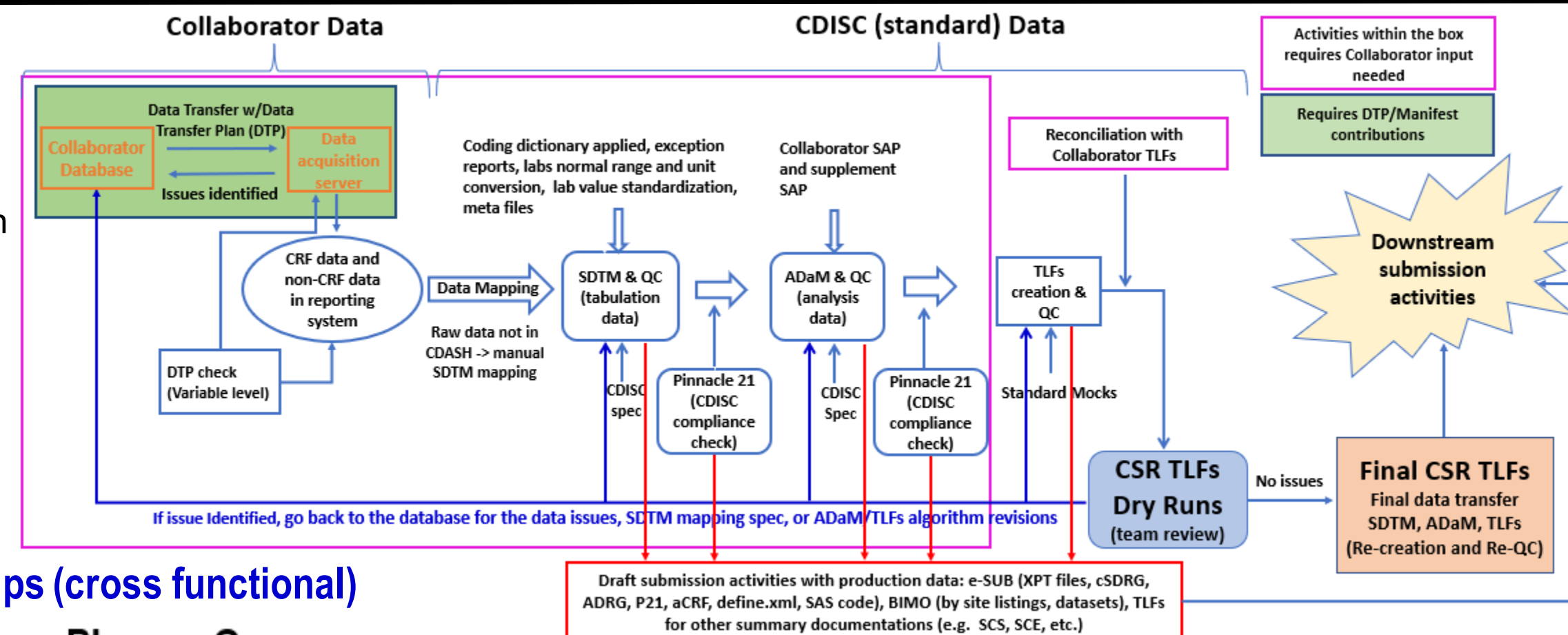
What? all collected data clinical/safety database, any external, meta data, and their associated documentation such as CRF, formats and specifications

When? Data transfer schedules has to be agreed through out study conduct

How? Data transfer method, unblinded vs. blinded, blinded study vs. open label

Which? Clearly describe which datasets are needed for what timing.

Annex: describing details associated with each data transfer including documentation and specifications



Submission technical challenges with CRC study set up..

Data collections:

- CRF design (non-CDASH, non-Pfizer standard)
- Data structure consistency across data transfers
- Understand collaborator database setup, functionalities and features
- Free text fields/Non-English/special characters
- Lab unit conversion and normal ranges
- Dictionary versions and coding
- CRF completion guidelines

Data availability:

- No accessibility to collaborator database and/or limited production data transfer
- Meaningful initial contract setup
- Request frequent high % of production data transfer and discuss protection of academic data integrity
- Consideration of open label vs. blinded studies
- Alignment of data transfer timing with the submission strategy
- More team discussion needed due to the non-standard nature of data collection and reporting to seek team decisions

Conclusions:

Contract clearly indicates when and what is needed and reviewed by right SMEs so the data can be used for regulatory submissions. Discussing the intention of the data usages with down stream programming activities with collaborator, so it is clear for the collaborator why frequent data transfer are requested. Close collaboration with your counter part in regular basis is key to have clearly understand the intention of the data usages, alignment of analysis results between 2 organizations and successful data reporting