



Innovate Clinical Trial Reporting with Open Source

PHUSE US Connect 2023

STORIES: ST08

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Our Storyline

Innovation through Reverse Engineering

Select published late phase clinical trial study

Deconstruct SAS® generated eCRT package

Statistical Programming Process flow chart with sequence of steps and deliverables

Shift from programming dependent to process driven
Department: Machine Readable Algorithms

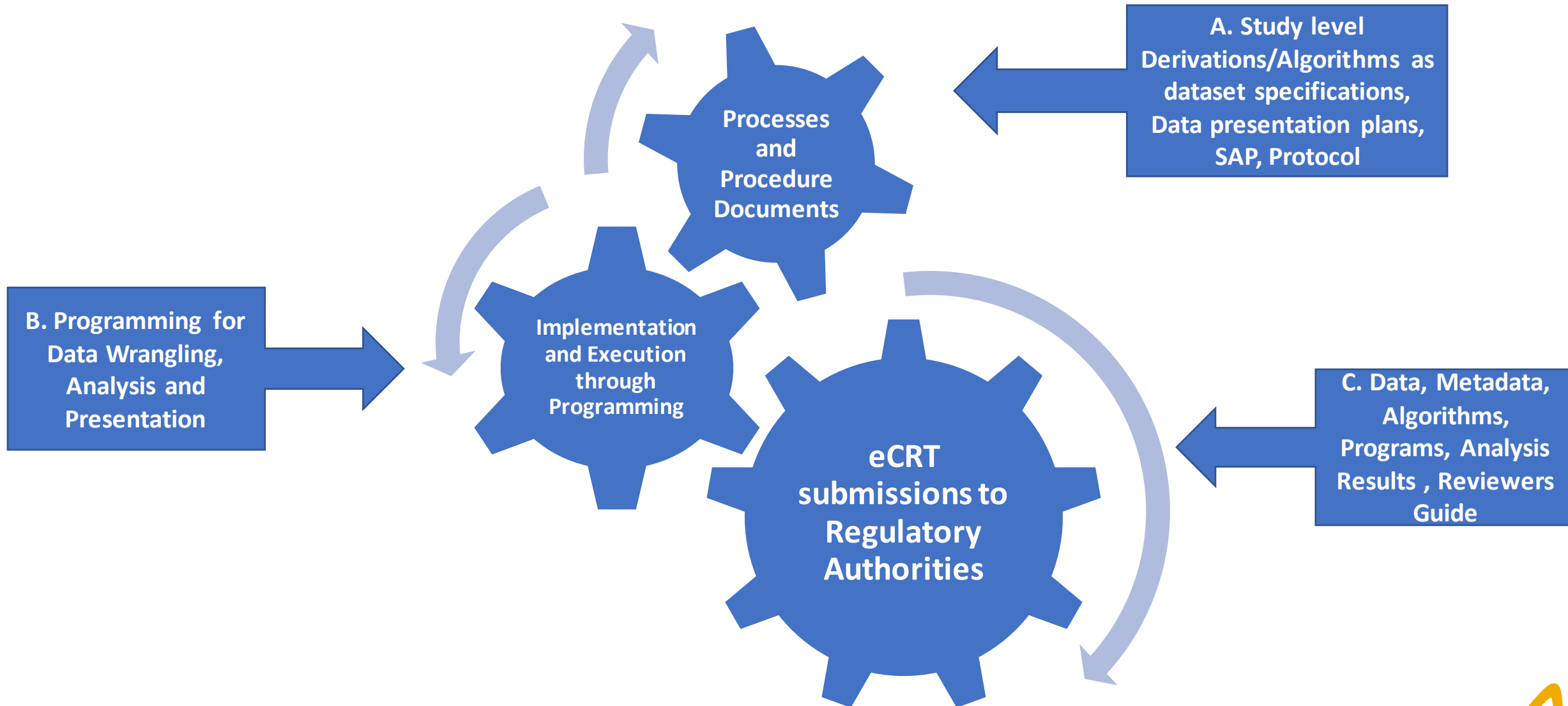
Recreate full or partial eCRT packages with
Open-Source Programming Language like R



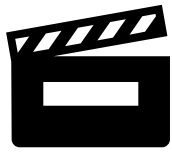
For the fifth year in a row, the DHL Fastest Pit Stop Award goes to Oracle Red Bull Racing



Reverse Engineering Plot



Take 1



PHASE I

Select
Submitted
(Approved
study) - eCRT

Rederive
ADaM
Datasets from
CSR SDTM-
OpenSource
Language (R)

Proc Compare (SAS®) with
CSR ADaM

PHASE II

Compare results with TLs,
Std.Err, p-values, rounding
issues? How to round?

Derive
Statistical
endpoints/pre
sent TLs –
multilingual
Mock shells

Generate Better
Interactive
Graphs?
(Rshiny-App
based graphs)

PHASE III

Validate all .r
programs,
CRAN packages

Recreate eCRT
package



Plot Twist

While we were working on our story discovered the need to shift to **Algorithms** based than programming based to detach **programming languages** from **Algorithms**



Outcomes	Population
Efficacy	
PFS1	FAS(ITT)
OS, PFS2, time to earliest progression by RECIST or Biomarkers or Death, HRQoL and PROs	FAS(ITT)
Safety Population/Demographics	
Demographics Characteristics	FAS(ITT)
Baseline and disease characteristics	FAS(ITT)
Protocol deviations	FAS(ITT)
Medical/Surgical History	FAS(ITT)
Previous Anti-cancer Therapy	FAS(ITT)
Concomitant Medications/Procedures	FAS(ITT)
Subsequent anti-cancer therapy	FAS(ITT)
Safety	
Exposure	Safety
Adverse Events	Safety
Laboratory Measurements	Safety
Electrocardiograms (ECGs)	Safety
Vital Signs	Safety



Innovation

Possibility of machine-readable documents (Derivations) within Statistical Programming – Algorithms

Example 1: Dataset Specifications – Manual excel file with Description of Data and Derivations

Example 1: Define.xml -Metadata (Machine Readable file and extract into a data structure)

Example 2: Data Presentation Plans, Programs to generate High level Results (end points)

Example 2: Analysis Results Metadata – Documentation for Statistical Analysis, results

Bridge must be any Programming language





Programmers work with Statisticians to develop SAP sections with clear guidance **Ex: How to Round, how to address differences between SAS® and desired open-source program steps to attain same analysis results**

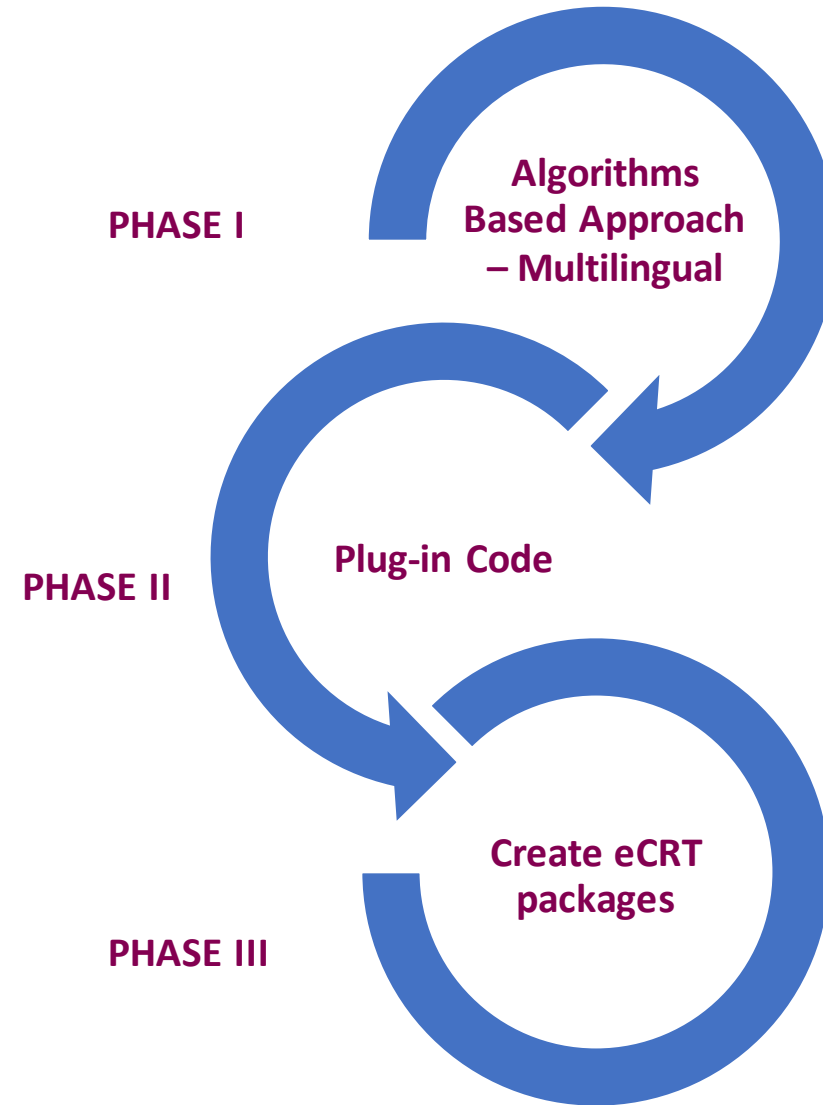
Write Dataset Specifications with Derivations in **simpler logical sequence /Natural language free of programming language/code** – Reusable and Consistent between similar studies; Consistent between multiple programming language; Machine Readable –**Defining Algorithms**

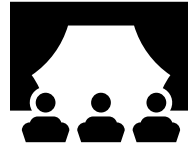
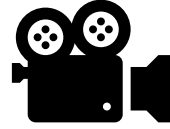
Test **Algorithms** with input data and output desired analysis results in different programming languages- **Multilingual Algorithms**

Write and **Validate Algorithms** to avoid bias while handling data.

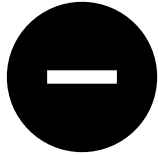


Take 2





Our Story



Not to compare or mimic Open Source with SAS® - **Rather to streamline processes**



To increase Statistical Programming efficiency and flexibility to be multilingual – **Diversity in Statistical Programming**



Test and Validate Algorithms – **Mitigate Risk to use Opensource programming within Clinical Trials**



Credits



AstraZeneca® – Oncology Biometrics

AstraZeneca® – R in Biometrics (Innovative Use of R) Workstream

AstraZeneca® - China Biometrics Team

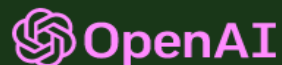
AstraZeneca® - Information Science Team

PHUSE® – Data Visualisation & OpenSource Technology - Clinical Statistical Reporting in Multilingual World Working Groups

R Consortium®

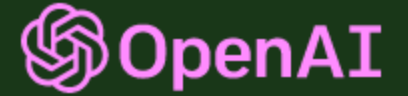
Statistical Software Clarifying Statement May 6th 2015– FDA®

Powered by ChatGPT®



Post Credit Scene

Powered by ChatGPT®



Algorithm.xml: If Slide number = 11 or Slide name = "Post Credit Scene" then print following text string: "Thank You."

OpenAI (Chat Box)

Programming Code in SAS, Python languages (Algorithms-to-Code)

Here's the SAS programming code for the algorithm you described:

```
java
/* Check if slide number is equal to 11, or if slide name is 'Post Credit Scene' */
if slide_num = 11 or slide_name = 'Post Credit Scene' then do;
  /* Print the text string 'Thank You' */
  put "Thank You.";
end;
```

Here's the Python programming code for the algorithm you described:

```
python
# Check if slide number is equal to 11, or if slide name is 'Post Credit Scene'
if slide_num == 11 or slide_name == 'Post Credit Scene':
  # Print the text string 'Thank You'
  print("Thank You.")
```



Q & A



Please go through our full length PHUSE paper for more information.

Contact:

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or questions.