

Digitalization, Agile Mindset, and Virtual Collaboration - Yet Delivering a "Pile of Paper"?

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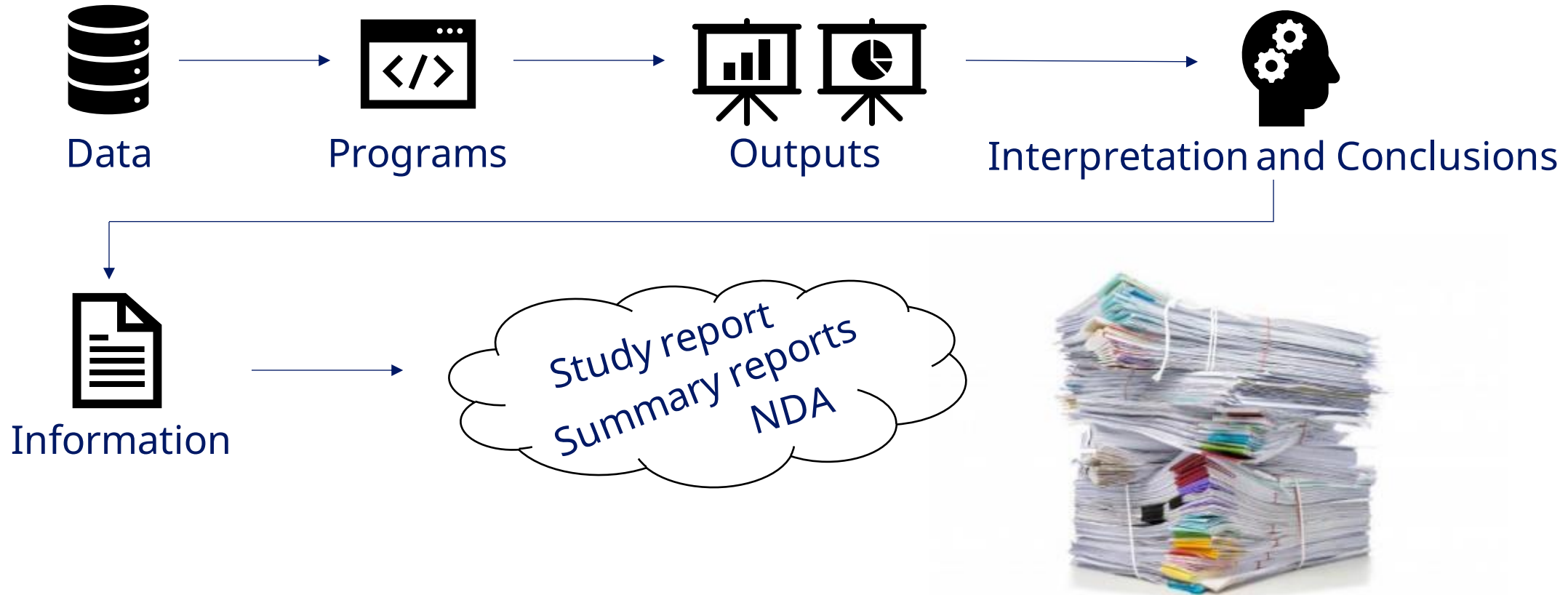
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14th -18th June 2021

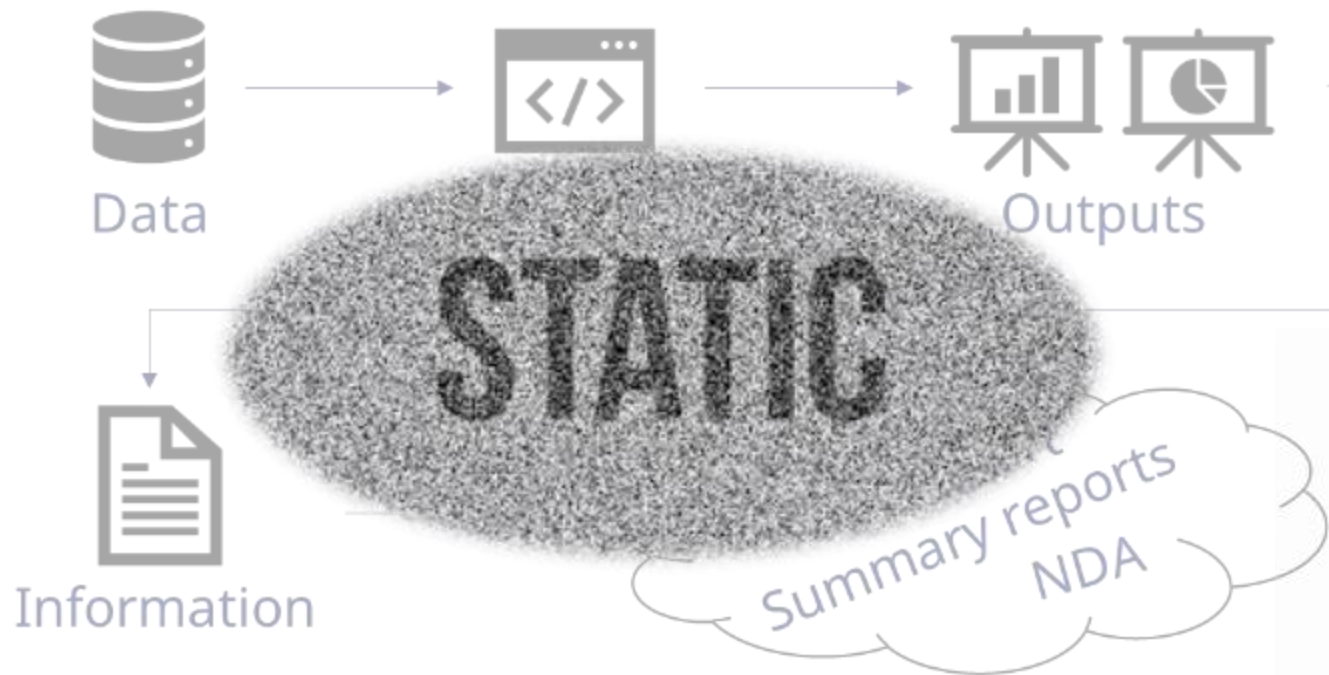
PHUSE US Connect 2021

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What and how do we deliver as of today?



What and how do we deliver as of today?



"That's what I hate about being a caveman.
Everything has to be carved in stone!"

What and how do we deliver as of today?

- Is everything that we prepare and submit, really needed?
- Is everything used?
- As an example, for FDA, we submit all SDTMs, then should listings be needed at all?
- In this world of digitalization, agile mindset and virtual collaboration – can we devise new ways of doing things?
- Can Big Pharmas and Authorities come together and redefine the traditional methods?

How do you define a 'good' program...

IT industry

- Efficiency and performance (memory and speed)
- Usability, learnability and overall user experience
- Portability
- Robustness and stability
- Security
- Reusability and interoperability
- Machine independence
- Maintainability and upward compatibility

Pharmaceutical industry

- Consistent reproducibility (for same input)
- Correctness through review
- Source code optimum to be reviewed and understood by human reader
- Credibility through traceability and transparency of data manipulations
- Reusability, but not if any of the above are compromised by it

Unique characteristics of a program in pharmaceutical industry

- A statistical program in the pharmaceutical industry context...:
 - does not need to have a user interface (no requirement for a front-end)
 - uses a static set of input (locked database) and produces a static set of outputs (datasets/TFLs)
 - only has to run once, hence no/low need on performance, portability, security

Unique characteristics of a program in pharmaceutical industry

- A statistical program in the pharmaceutical industry context...:
 - does not require extensive test sets, as it needs to work only on a fixed data foundation (locked database)
 - works only as a supplementary reference documentation on the analysis performed and there is no requirement or expectation for the program to be executable
 - is not one of the main deliverables – the output it generates is the main deliverable (however, programs may be submitted for review)

Approaches to data cleaning and processing

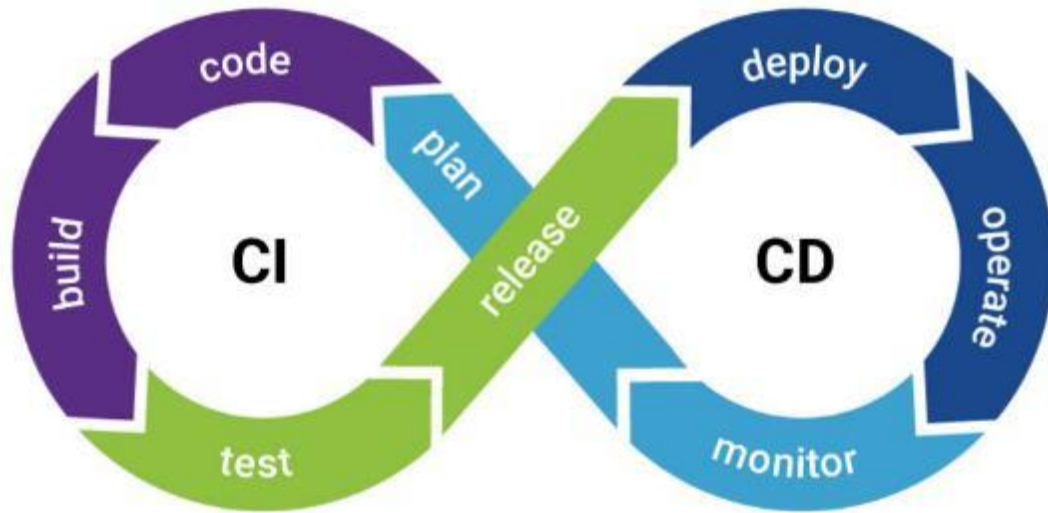
Pharmaceutical industry

- Missing data
- Data derivation rules
- Partial date and time, date and time imputations
- Timepoint characterisation, visit reallocations

Other industries

- Business rules – e.g. interest rate calculation
- Volatility and Volume - e.g. data in stock exchange
- Requirements in terms of completeness – e.g. banking transactions cannot have a missing or partial date

CI/CD and MVP



Continuous Integration and
Continuous Delivery or Deployment

Minimum Viable Product



Approach lacking MVP

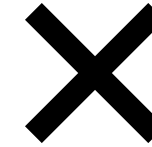


MVP Approach

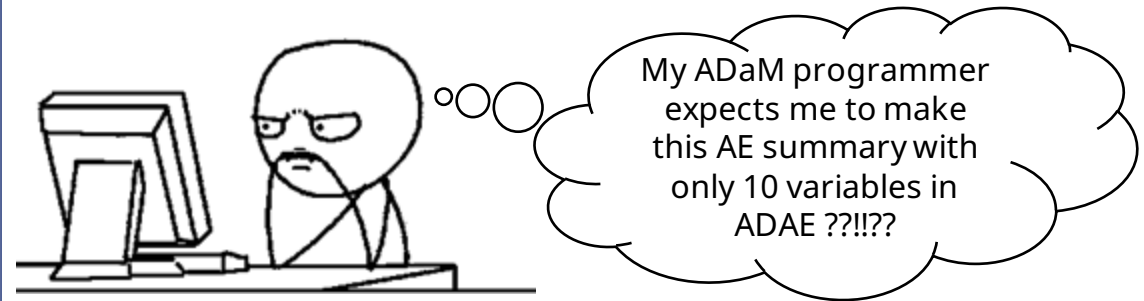
CI/CD and MVP in pharmaceutical industry



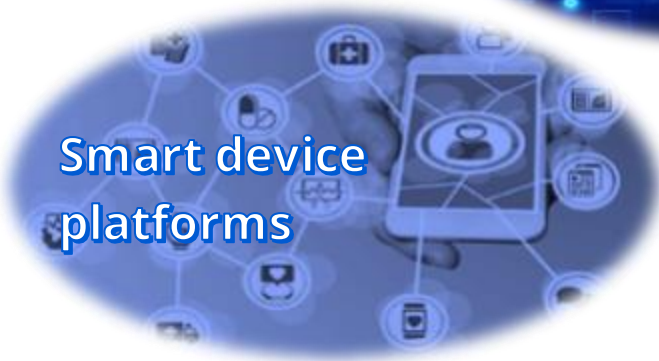
- Company level standard macros
- Functional utilities e.g. a Log checker
- Template programs
- Guidance documents
- Enabling solutions e.g. project management tools, revision control systems, visualisation tools



- ADaM datasets, outputs
- Exploratory outputs with short timelines
- Outputs for authority feedback



Riding waves of a new era



Riding waves of a new era

- Increasing volume of data
- Patient centric smart devices and trackers
- Emerging trends, technologies
- Modern project management tools
- Powerful visualisation tools
- Dynamic dashboards
- Artificial Intelligence
- Machine and deep learning
- Natural language processing



Taking transformation to the final product



- Dynamic and real-time data review (internally and possibly by authorities)
- Fixed static package for key outputs
- Dynamic packages of data and apps for everything else
- Can pave way for authorities to get 'executable and interactive' packages
- Utilizing visualizations to the highest degree possible – as a part of trial conduct and submission
- Automation of standard deliverables (reviewer guide, define)

Balancing disruptive transformation and current processes

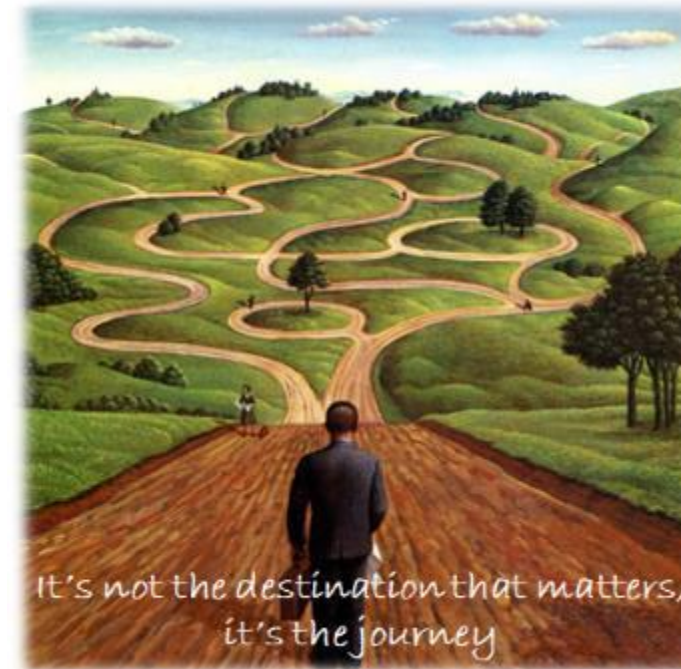
- Duration aspect – Long running programs with multiple trials done using a particular process model
- Continuity aspect – Cannot upgrade your car while driving it
- Timeline aspect – Important to not drive off the critical path
- Greater goal – Outcome of the trial is more in focus than tools or processes that enable us to conduct and report the trial
- Parallel experimentation – Transformation needs to be in parallel with a minimum overlap with 'ongoing' activities (a separate focus group re-reporting older trials using new methodologies)



Conclusion

We are all on a transformational journey,
exploring new roads and moving away from the
norms...

We are completely changing the way we travel...



What is equally important is that we
change the destination itself!

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