

Single Day Event

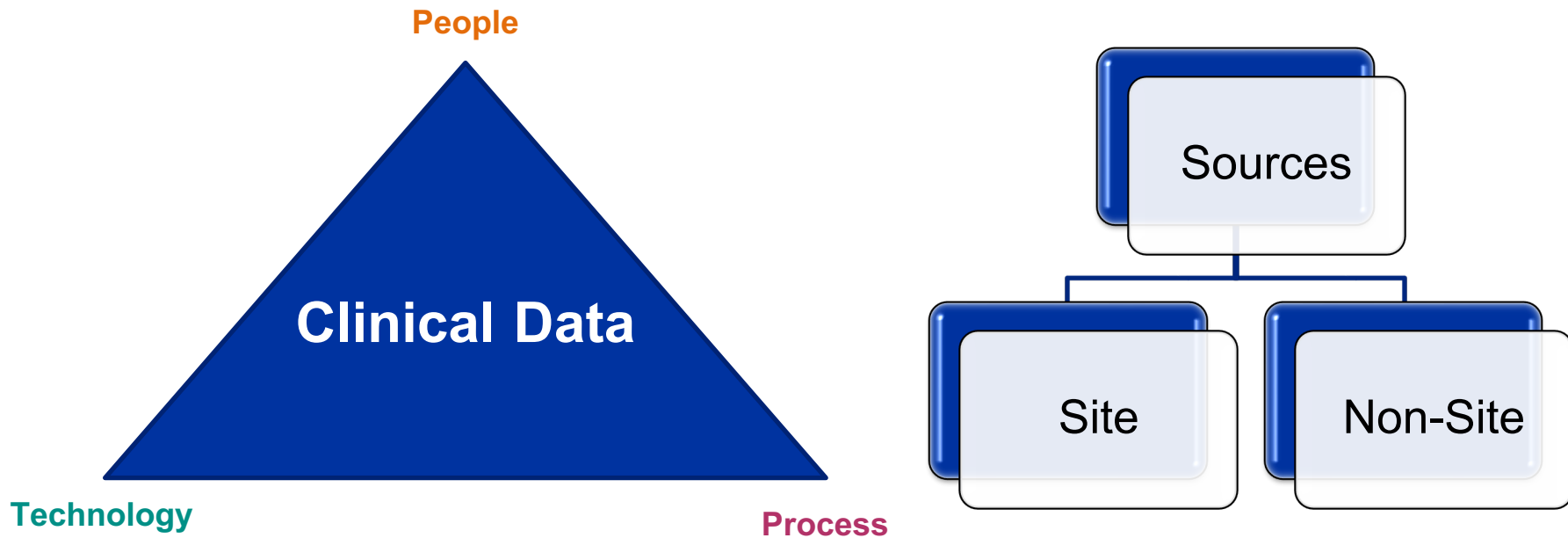
Integrate and harmonize Technology (T), People (P), and Processes (P) (TPP) for improving quality, and gain efficiencies in clinical data submission datasets, CDISC/Non-CDISC

Nikunj R Patel,
CBCC Global Research

Disclaimer by the speaker

This disclaimer informs readers/attendees that the views, thoughts, and opinions expressed in the talks are of the speaker, and not necessarily directly or indirectly imply of the speaker's employer, organization, committee or other group or individual.

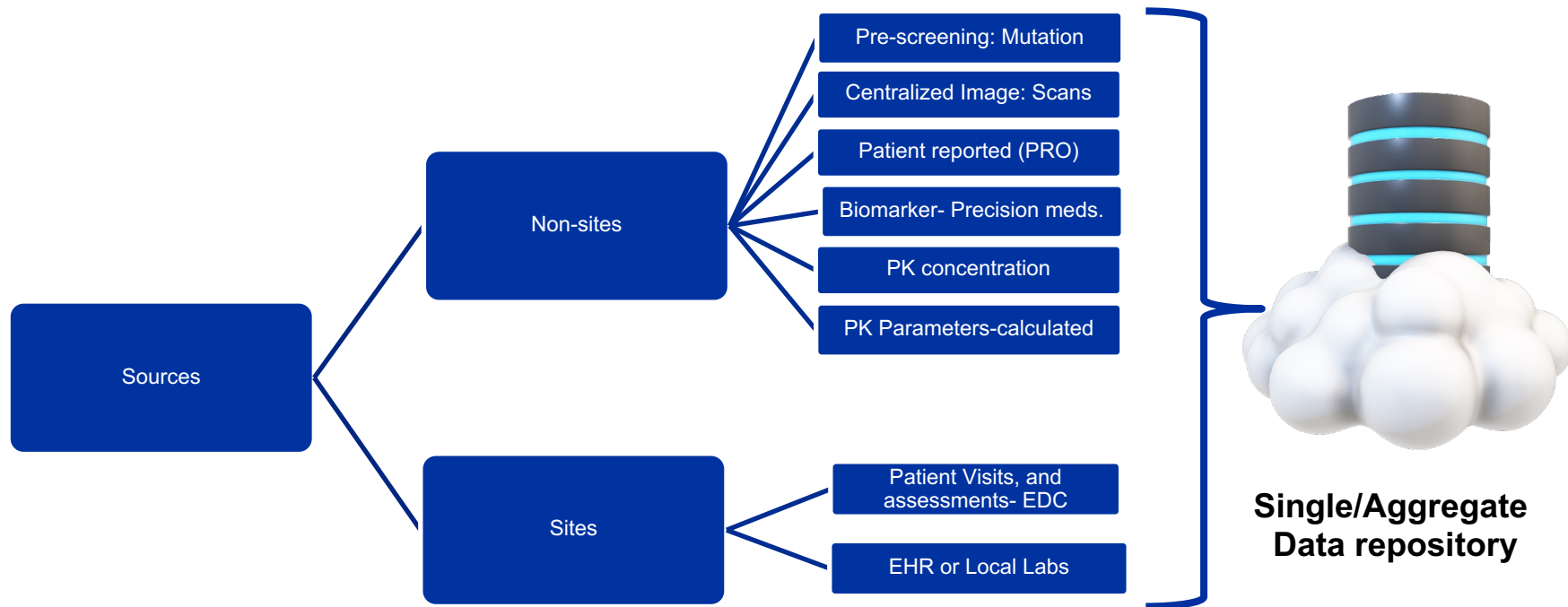
Clinical Data



Three pillars and different sources of the clinical data



Sources, and bringing at singular location from diverse data suppliers



Diverse and multiple clinical data sources brought together at one place from the sites and non-sites



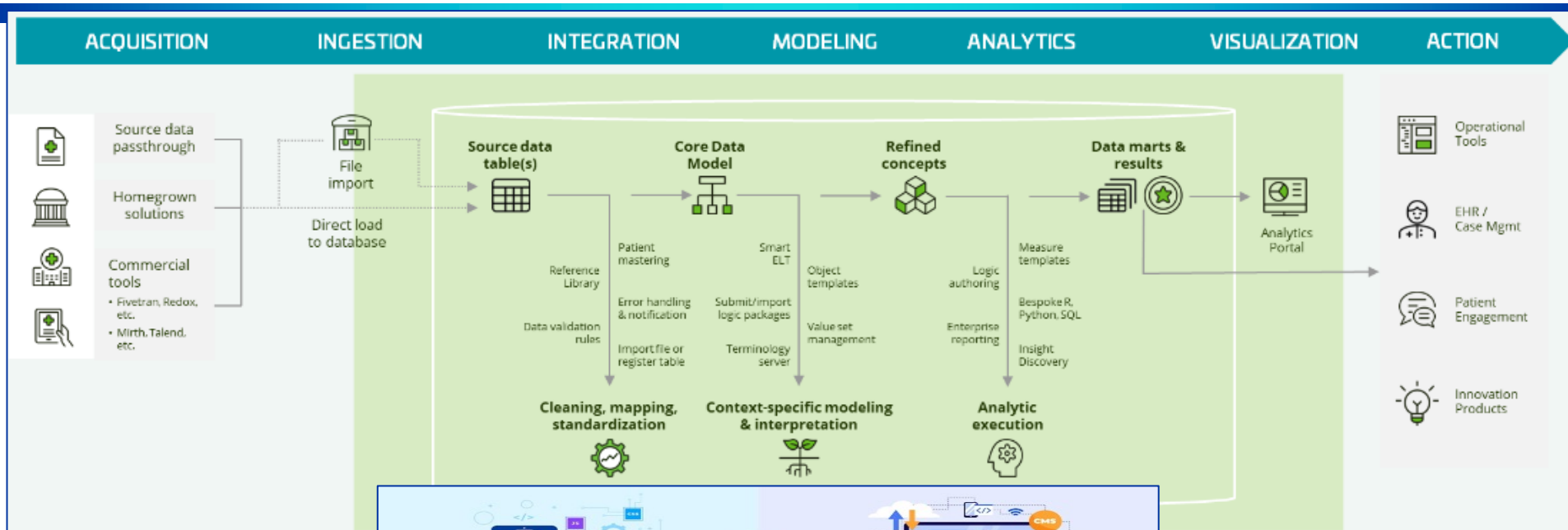
Conformance expectations of CDISC or non-CDISC standards

- The fully validated, integrated, and advanced manipulation tool should have features:
 - No programming language knowledge required
 - Renaming or remapping of variable names from reporting to CDISC standards
 - Renaming of variable code list
 - Re-ordering of visits
 - Calculations of day, and date assignment
 - Addition of variables with both, annotations, and label with merging information
 - Graphical, and analytics presentations of the summary or individual patient data
 - Consolidated/study level safety, efficacy or patient level profiles or one or more panels in the following formats:
 - .XPT
 - Word
 - Excel
 - PDF



Data Life Cycle from Acquisition (A) to Action (A)

Evolving from coding language to non-code dependent

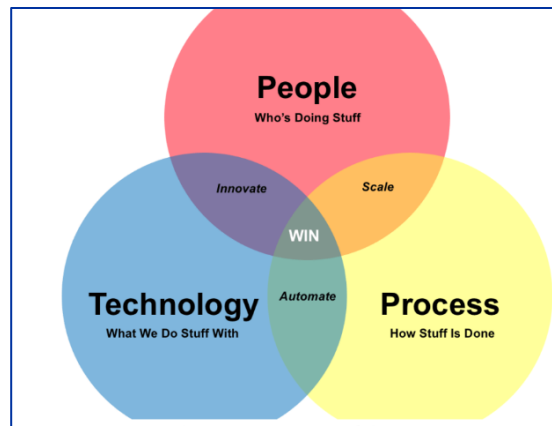


<https://www.ursahealth.com/>
Google, web sources



Impact of changes in Technology, People and Process

- Technology enablement, a fully validated, integrated, and advanced data manipulation should give following:
 - Automated mapping, with audit trail
 - New variable report outputs, with audit trail
 - .XPT outputs creation
- People:
 - Role changes from manual mapping specifications to reviewing the outputs
 - Limited or no programming knowledge requirements for datasets creation
- Process:
 - New SOPs will need to be written meeting above expectations
 - Changes in the roles of technical DM to SDTM, ADAM report reviewer





Summary: Take home message

- Revamp the current approach by exploring more technological advanced solution
- A right way of confluence for bringing out better and optimal solution by bringing Technology (T), People (P), and Processes (P) (TPP)

Concluding thoughts or name of solutions in mind of the audience and/or speaker

Thank you



The Global Healthcare Data Science Community

Contact Channels

- UK +44 1843 609600
- office@phuse.global
- phuse.global

Social Media

- @phusetwitta
- /phusebook
- /phusetube
- /company/phuse