

Statistical Programming Validation from a Small Biotech Perspective

PHUSE Single Day Event

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Topics

- Validation and ensure Quality
- Sourcing model in small biotech
- Keep quality in mind through the project life cycle
- Examples of challenges and solutions
- Q & A

Why do we
do
validation?



Ensure Quality

Big Pharma or CRO

Sourcing Models in Small Biotech

Total outsourcing



Projects can be outsourced, but NOT
quality

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Keep quality
in mind
through the
project life
cycle

- Vendor selection
 - Manage and guide your vendor
 - Build the relationship with your vendor
 - Motivate your vendor to own the projects
 - Sponsor step by step review
 - Sponsor validate key deliverables
 - Quality assurance
 - Accept vendor's work
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Vendor Selection

- Use the same vendor as Clinical Operations and Data Management
 - Easy to manage
 - Need to assess the statistical programming capabilities
- Identify a different vendor from the study main vendor
 - Easy to control budget
 - Need to coordinate and communicate between different vendors.





Manage and guide your vendor

- Provide the background of the project, like disease area, the drug mechanism of action, rationale of the new therapy, competitors, etc.
- Make sure the vendor statisticians and programmers know the study and the analyses.
- Clearly state the expectations from your vendor, high quality and on-time deliveries should always be the focus.
- Provide guidance for certain mappings, definitions or modeling, etc.
- Monitor vendor's strength and weakness

Build the relationship with your vendor



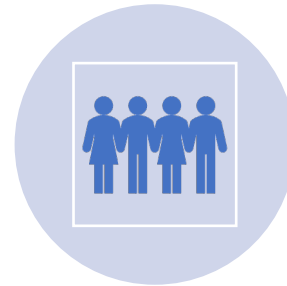
Good relationship is the catalyst to boost vendor's performance.



With the good relationship, one vendor can work on multiple studies, which dramatically save time and money.



Easy to manage the budget and save overhead time to select different vendors.



Respect each other, work as a team, and support good team culture

Motivate your vendor to own the projects



Ownership is the key for a successful project



Vendor's ownership will motivate each programmer to do critical thinking, identify the root cause of issues, raise meaningful questions, and have good discussions with sponsor cross functional teams.

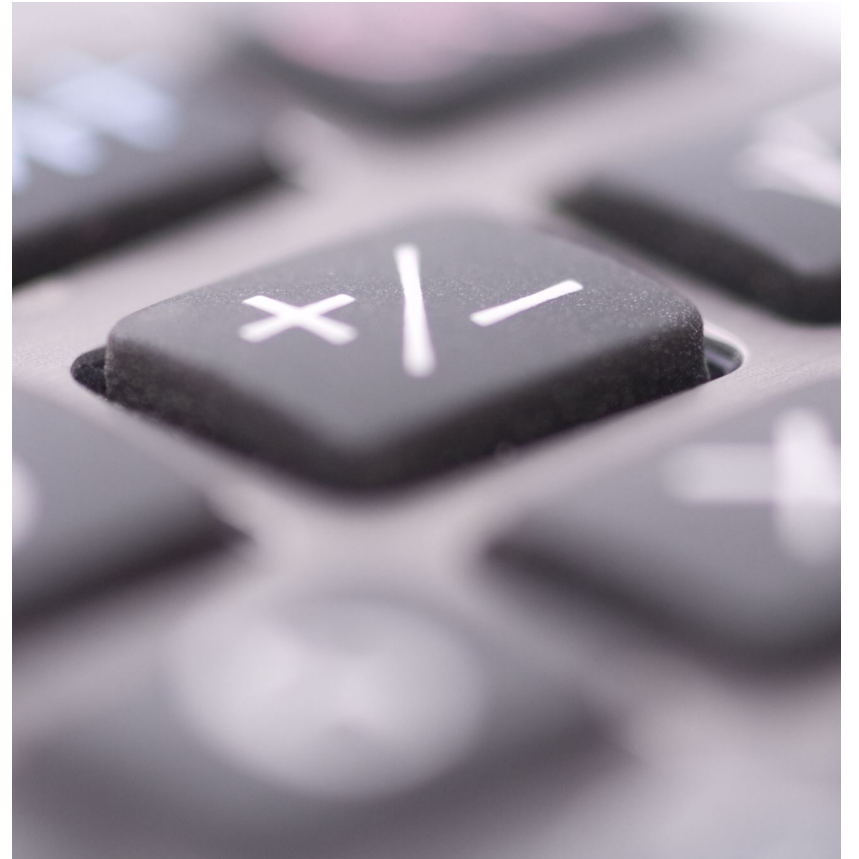


Sponsor has the ultimate responsibility of the quality of the project, but vendor's ownership will dramatically improve the quality.

Sponsor step by step review

Sponsor validate key deliverables

- Strongly suggest sponsor to validate the SDTM, ADaM datasets, TFLs for primary or secondary endpoints.
- Statisticians should pay special attention to the definitions of the key variables, and validate the critical tables
- It is impossible to validate each dataset or TFL, but a reasonableness or consistent check should be performed for other results.
- This is the process to motivate and train sponsor staff, Re-emphasize that sponsor has the ultimate ownership of the project.
- This also serves the purpose to identify risk and do risk mitigation.



Quality assurance

- Quality assurance is a systematic process to determine the quality of the services.
- The datasets, TFLs or define package have already passed vendor's QC. Quality assurance is to ensure the production and QC were done properly.
- Critical logic checklist and cross checks for consistency are important to do the systemic check.



Accept vendor's work

Ensure the whole project was run sequentially, e.g. SDTM – ADaM – TFLs

Pinnacle 21 messages can be accepted or explained

Define package follows the most updated agency or CDISC requirements.

TMF was loaded for Biostat/programming items

Examples of challenges and solutions (1)

CHALLENGES

No designated team position due to limited resources

- Validate multiple projects or collaborate with multiple vendors at the same time, especially work on projects at different stages.
- Have extensive knowledge on industry standards, regulations, and guidelines
- Highly skilled at macro coding and other utility coding

Limited support from other functions

- Comparing with big pharma, may have more data issues to deal with due to limited resources on data cleaning.
- Lack of clear instructions or guidance due to resourcing shortage in other teams
- Technical issues on servers, data transfers from vendors, etc.

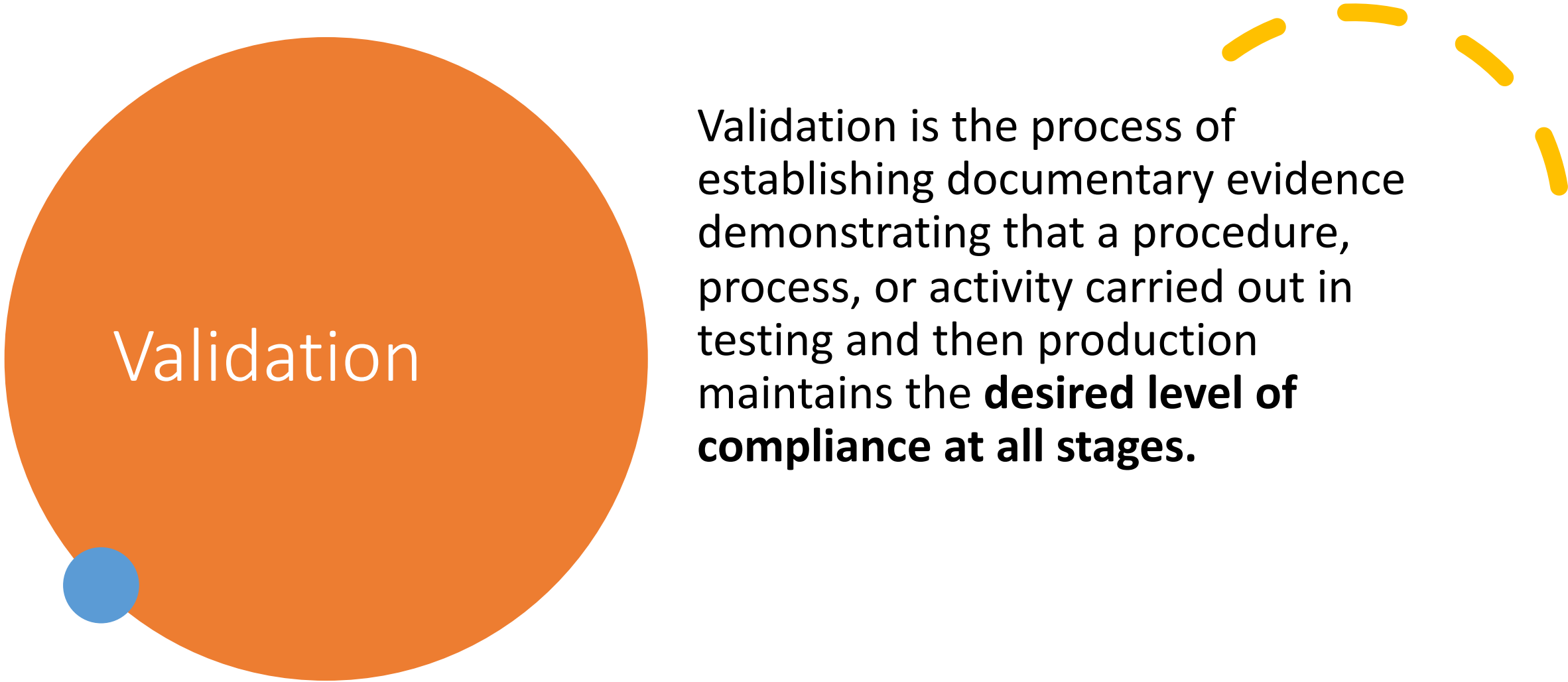
SOLUTIONS

- Management team develops the hiring strategy
- Provide customized training.
- Develop validation tools and techniques to save resources.

- Utilize programming tools to facilitate data cleaning.
- Engage the stakeholders early and regularly.

Examples of challenges and solutions (2)

CHALLENGES	SOLUTIONS
Timelines and priorities change frequently and rapidly • Less time to review and validate deliveries as Vendors often can't delivery as planned. • Hard to adjust priorities and relocate resources due to conflict timelines. • No enough time to plan and prepare	• Programming lead should be in the strategy meeting, keep the communication channel open. • Split deliveries into batches, closely communicate with vendors on the progress. • Fully utilize vendor's resources and utilities. Get support from other functional teams.
Lack of standards and programming infrastructures • Very limited data standards and output format standards. • Lack of tools and reusable programs. • Some validations have to be done manually when no tool is available.	• Utilize vendors' data standards and revise based on database design and analysis need. • Develop robust programs and build up programming libraries and infrastructure. • Start a validation plan early and develop supporting tools ahead of time.



Validation

Validation is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the **desired level of compliance at all stages.**



Q & A

