PRAHEALTHSCIENCES

THE FUTURE OF CLINICAL DEVELOPMENT

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What is Validation?

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Disclaimer

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Users don't know what they really want, but they know for certain what they don't want

Survey/Interviews

- Check for correct counts
- Ongoing till final submissions
- Validation is verification
- Kind of ensuring whatever was intended do again and again
- Checking the quality of the program frequently

Q AL TY

- Regulated Industry - GxP systems

  (Current) Good Manufacturing Practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing organisation(or product specification)

- QA and QC???

  "……all activities necessary to verify confidence in the quality of the processes used to manufacture a finished device".

- Validation??

  The basic principles of quality assurance have as their goal the production of articles that are fit for their intended use.

  Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

Validation

- Doing it without knowing what is it?
- Examples???

  Watch, thermometer etc.

  Consistent, accurate, specific, robust
  IQ/OQ/PQ

- SAS programs???
- What are the intended use?
- Requirements – specifications
- No clear-cut process mentioned
- Companies follow it differently(no unique process)

Validation

"Process of assuring the user (MW/FDA) that the outputs generated through a program is(are) a true reflection of the data collected thus far".

"It is hard to define GOOD quality and poor quality is glaringly evident"

Valid-validity-validation

Armories

- Input – process – output model
- Understand – what is expected
- Imagine all scenarios(Robust)
- Cases of count(s) not matching within and between tables, population definition
- Incorrect interpretation of specifications

Experience

- I am happy when no one comes back to me!
- Instances where some “well written” programs need to be revised
- FDA had raised lot of queries which were never thought of
- Serious problems detected while reviewed by others
- “Done in a hurry”

Types of Errors

- Understanding of specifications
- Interactions within the program/macro resolution
- Logical errors, data errors, coding errors
- Cases of count(s) not matching within and between tables, population definition
- Wrong specifications E-g: banking, airplane landings etc.,
- Understanding of responsibilities

Process

- Developer/Validator??? Who is responsible?
- Testing when is it done?
- UAT- what is it? (Expected results)
- Robust against extreme values, bad data, strange data, missing data, large volume etc.,
- Everything in our scenario is dynamic and not static
- Simulate the experience

Thank You