A New Norm - Higher expectations from present Statistical Programmer

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Jun2021

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AGENDA

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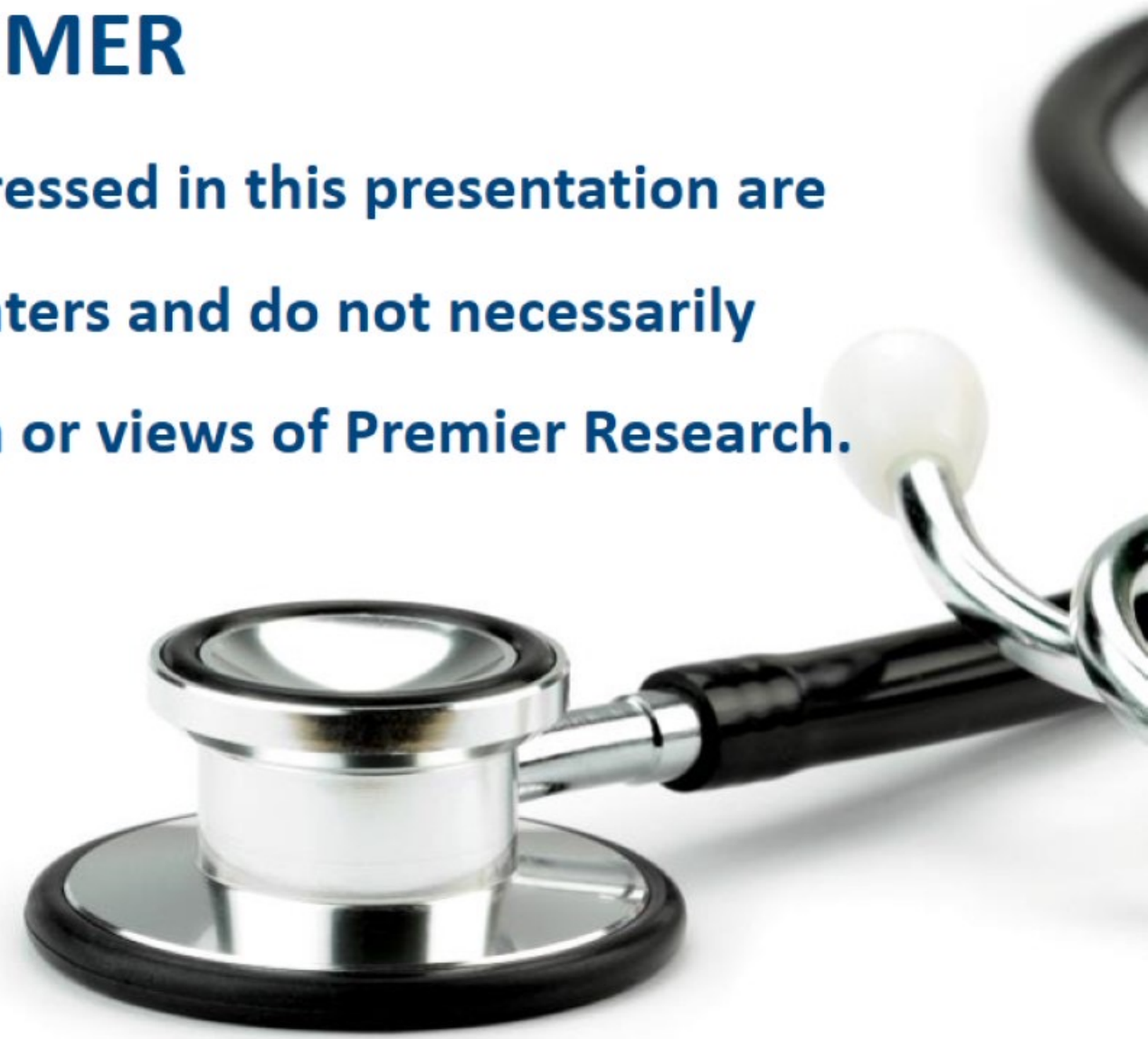

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ABSTRACT

Once upon a time…. role of a Statistical Programmer was to create static datasets/statistical outputs based on specifications and/or mock shells. Their approach used to be task oriented and stakeholder management mostly limited to the Biometric team.

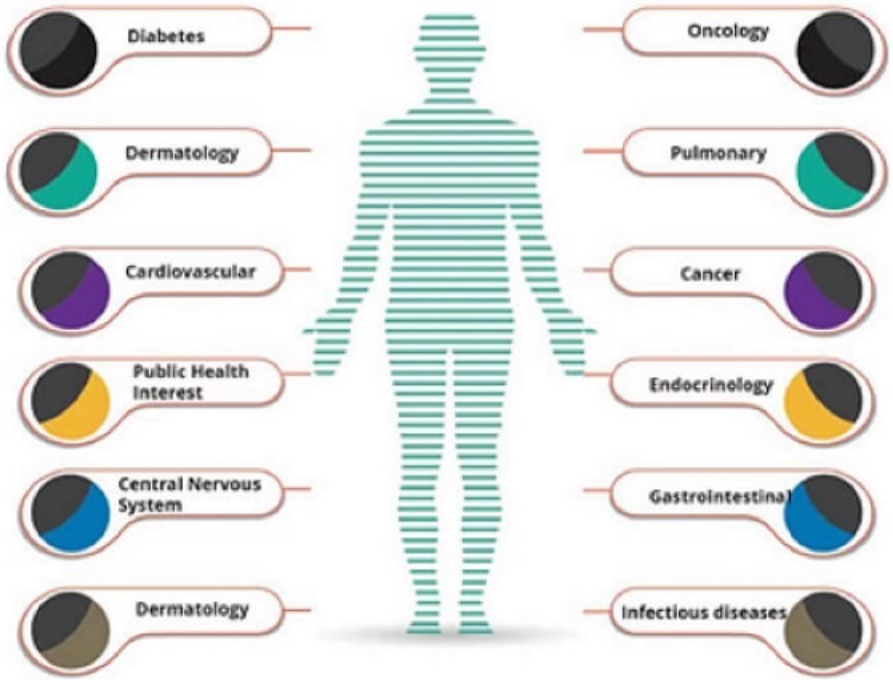
Fast forward to present times, there has been a sea change in drug development process with big data, new strategies, new technologies, adaptive/complex trial design and novel endpoints for getting therapies to patients faster with reduced cost and shorter timelines.

In this new landscape, the Statistical Programmer are expected to un-learn waterfall methodology, re-learn and adapt to Agile methodology and offer solutions to solve complex problems in real-time across all stages of drug development lifecycle, strategize with key decision makers and collaborate with operational stakeholders.

It is a new norm, for today's Statistical Programmer to provide the innovative statistical methodologies, dynamic visualizations, evidence-based and data-driven insights, diverse programming solutions & reusable standards and we are expected to be up in the value chain.

Deep understanding of the therapeutic areas

- Conventionally, programmers tended to be experts only in programming, did not think much about pharmaceutical domain.
- Currently, statistical programmers are expected to understand much more about the therapeutic area in which they are working.
- Therapeutic areas like oncology , vaccines, cardiology, gene therapies have a huge landscape with complex and sophisticated methods.
- It's very important for the statistical programmers to understand how these therapies work to perform the most effective job.
- With this current COVID pandemic, pharma companies are in heavy need of the SP to have an expert knowledge in the vaccine trails so they can bring the drug to the patient much fastly and efficiently.

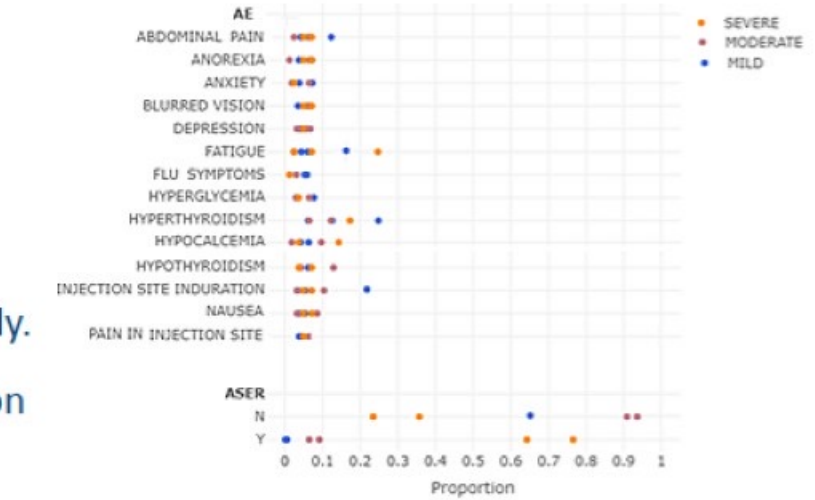


CROSS-FUNCTIONAL collaboration

- As the cost and complexity of clinical trials continue to rise, the sponsors are looking for ways to drive efficiencies.
- One of the ways to increase efficiency is through a collaborative cross functional approach from the early stages of a project.
- The SP's are also expected to review the protocol early along with statistician to drive efficiency during the project.
- An experienced biometrics team that is familiar with regulatory guidelines in target therapeutic areas could help improve the quality of trial design, study procedures and analysis methods.
- The Biometrics team are expected to be a strategic partner, provide guidance, and help with planning in every stage of a study.

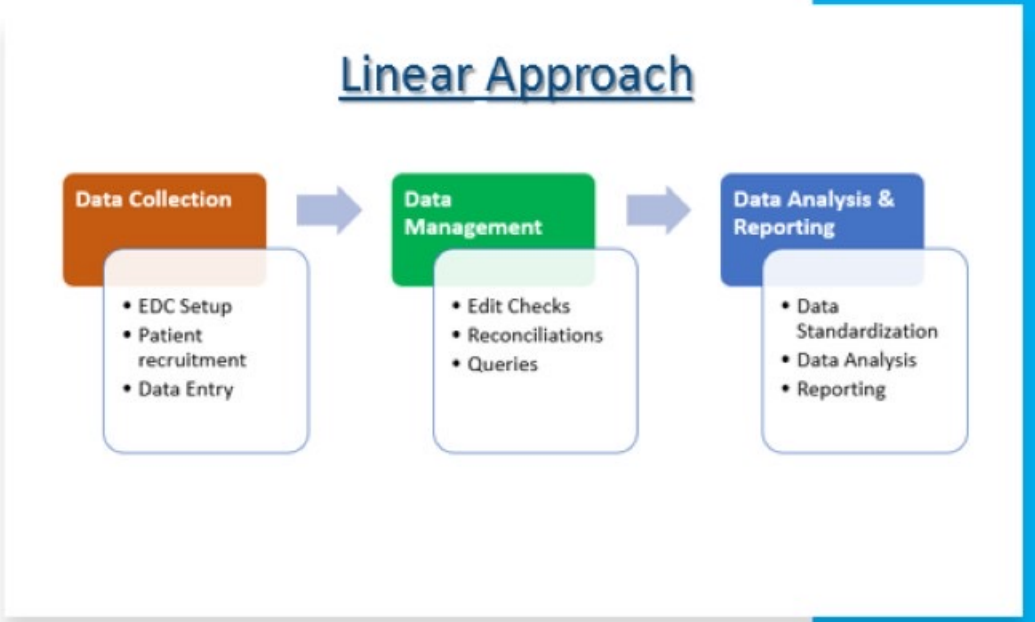
Innovation and Adaptation

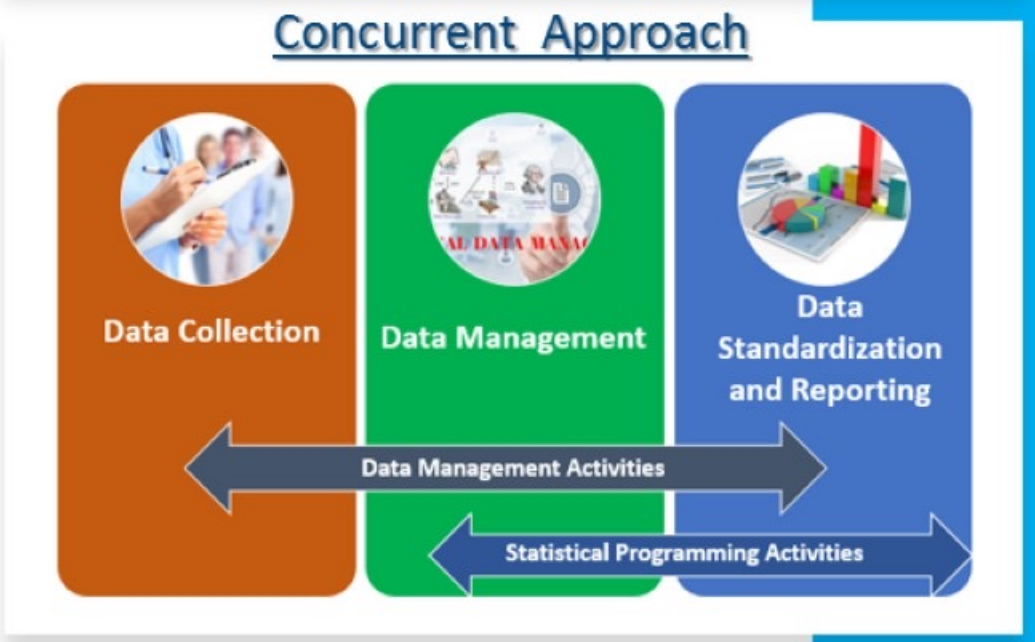
- In clinical trials, a good deal of efforts goes into producing both final trial reports and interim reports for DMC/DSMB.
- The sponsors are looking for better alternative Technology & Tools which provide better Insights on data and can help improve decision making quickly.
- In this current pandemic situation, sponsors have shown much preference on interactive graphical reports than static tabular reports for the better visualization of data.
- In recent study, we have utilized the R Shiny and R data visualization capability to produce the Interactive reports which allow the reviewers to thoroughly investigate and monitor the critical data for the patient safety and accuracy.
- This helps the clinical team to take critical decisions regarding continuation of subjects in clinical trial and it helps to identify potential sources of data inconsistencies in an efficient manner.
- R's harrelfe/hreport package contains many functions useful for monitoring and reporting the results of clinical trials.



Deal with Unclean data

- Traditionally, the life of a clinical trial data assumed to occurs in a linear model.
- However, In practice, these processes run simultaneously, as CDM does not wait for all data to be collected before commencing with their cleaning and reconciliation tasks.
- Statistical programming does not wait for a clean database prior to developing the programming setup needed to standardize the data and produce the TLFs.
- The contemporary nature of these activities creates additional challenges and opportunities for efficiency and quality improvements for the entire clinical trial data.
- In our recent study, we have performed the holistic review of the clinical trail data using the statistical reports supporting the data analysis and data cleaning.
- Data anomalies like missing patients, doses, visits, results out of range values are identified and reported to CDM team.





The provisional statistician

- The Statistical programmers play a vital role in converting the clinical trial data into information which supports the new drug development.
- With this evolving high industry expectations, the role of Statistical programmers is evolving to become more multifaceted, not restricted only to the programming.
- The role of statistical programmers is overlapping with the role of a statistician as we have statistical programmers with good experience in statistical programming, some have advantage of statistics degrees.
- In this current Industry norm, the strong statistical programming experience and the statistical basics is adding value to these statistical activities such as the creation of mock shells and review of the SAP.

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Adhoc Analysis

- It is common practice for any clinical trials to include a plan for interim analyses of the data, and to monitor safety.
- An interim analysis may be designed into a clinical trial at a predetermined point for many reasons, whether the IP is efficient, or whether it is safe and the decision to continue the study or to terminate it prematurely.
- In the recent studies, the IA has been more dynamic in nature and that is triggered based on the event rather than the predefined timepoint.
- For Example: -
  - For COVID studies,
    - when xx number of subjects who got RT-PCR positive
    - when xx days after xx number of subjects taken the Dose
  - This adhoc analysis always comes along with the challenges for the statistical programming as there will be uncleaned data in the database and it is expected in the very short timeframe.

- The statistical programmer is a vital member of any clinical trails as they support getting insights from data.
- The programming and analysis landscape has evolved, and programmers require to develop their technical and behavioral competencies.
- The future is going to be even more challenges, including more new data types, increasing innovations, complex trial designs and shorter timelines.
- The programming and analytical skills are imperative, conversely the ability to adopt new technologies, collaborate with cross functions, TA knowledge, project management and decisions making is even more critical.

Any Questions ?

Thank You

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