

JumpStart

An oncology reviewer's take

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Disclaimer: This speech reflects the views of the speaker and should not be construed to represent FDA's views or policies

NDA/BLA reviews in oncology

- Priority reviews are common
- Breakthrough therapies
- Some applications reviewed faster than priority designation
 - Nivolumab approved ~ 3 months ahead of goal
 - Blinitumomab approved ~ 5 months ahead of goal

JumpStart can streamline reviews

- Clinical reviewers (generally) are not SAS programmers
- Many clinical reviewers analyze data via
 - JMP (different from JumpStart) or
 - JReview

JMP

- Pros
 - Generally easy to learn (but hard to master)
 - Data right in front of you
 - Can use with any type of data
 - “Malleable” (e.g., one can write their own formulas)
- Challenges:
 - Can take time to set up certain analyses (e.g., shift tables)

JReview

- Pros
 - Can perform analyses across datasets (e.g., without joining)
 - Graphical patient profile capabilities
- Challenges
 - For some reviewers can be harder to learn (e.g. more logic functions)



JumpStart

JumpStart and JReview

- Use of JReview is complementary
- Allows exploration of certain signals (e.g., MedDRA SMQs)
 - What PTs are driving an SMQ (true agranulocytosis vs. chemo-induced neutropenia)
 - Differential effects in subgroups

JumpStart

- Pros
 - Quickly assesses quality of the data
 - Quickly performs certain standard analyses
 - Demographics
 - Adverse events across the MedDRA hierarchy
 - SMQ analyses
 - Certain lab analyses (especially liver)

Pros continued

- One can place certain analyses directly into review (more time analyzing data, less time manipulating data)
- Can get nice visual outputs to facilitate the analysis and review of data

Analyses across MedDRA hierarchy

- Important in review
 - e.g., describing safety in labeling
- Analysis at preferred term level may underestimate incidence of an AE
- Datasets in NDAs/BLAs often include only verbatim terms, PTs, or SOC
- JumpStart allows for rapid analyses with different tools

JumpStart

- Cons
 - Only works with standardized data
 - Does not obviate the need to use JMP, JReview, SAS (or other) for some safety analyses
 - Numbers may not match Applicant's
 - JumpStart uses SDTM (not ADaM)
 - Often due to differences in standard treatment emergent flag used by the Agency