Submission of Programs to authorities

14 March 2023

Submission of Programs to authorities

- Programs should be part of delivery packages that are provided to regulatory authorities

- Requirements differ slightly by authority
  - FDA and PMDA provide rather detailed guidance
  - EMA does not provide any guidance at all
  - NMPA provides (slightly vague) details in their Jul-2020 guidance

Submission of Programs to authorities

- FDA requirements (https://www.fda.gov/media/153632/download):
  - Programs covering any of the following should be submitted:
    - All ADaM datasets
    - Tables and figures associated with primary/secondary efficacy analysis
    - Any source code used to generate additional information included in section 14 CLINCIAL STUDIES of the Prescribing Information
  - The software used (version and operating system) should be specified in the ADRG
  - No mention if programs must be executable or not (Macros thus might not need to be submitted, if described in ADRG)
  - Programs provided to FDA must be in single byte ASCII text format

Submission of Programs to authorities

- PMDA requirements (https://www.pmda.go.jp/files/000247157.pdf):
  - Programs covering any of the following should be submitted:
    - All ADaM datasets
    - Tables and figures showing “important” results on efficacy and safety (i.e. primary/secondary endpoints)
    - Tables and figures producing the clinical study results that provide the rationales for setting dosage and administration levels
  - The software used (version and operating system) should be specified in the ADRG
  - Would prefer to receive macros as well but concede that this might be possible
    - Providing specifications showing the used algorithms (in ADRG) is sufficient
  - Programs provided to PMDA should use the extension attached by the respective software (i.e. .sas is accepted)

Submission of Programs to authorities

- EMA requirements:
  - None
- NMPA requirements (from the July-2020 guideline, effective since Oct-2020 https://www.lexjansen.com/pharmasug/2021/SS/PharmaSUG-2021-SS-073.pdf):
  - Programs covering any of the following should be submitted:
    - All ADaM datasets
    - TFLs covering primary and secondary efficacy endpoints
    - “etc.”
  - Programs must be readable (with comments), understandable, executable, and not include external program calls
    - Particularly the use of “external macro programs” should be avoided
  - Programs should generally be provided in TXT format

Submitting programs in deliveries

- Summary:
  - SDTM programs not required to be submitted
  - All production side ADaM programs should be included
  - All production side Tables/Figure programs that support primary/secondary endpoints should be included
  - Macros should not be provided normally
  - Follow good programming practice throughout the project to ensure that programs fulfill the readability and understandability requirement
  - File extension:
    - For PMDA as .sas
    - For all others as single byte ASCII .txt

Submitting programs in deliveries

- Summary:
  - In ADRG:
    - Provide the SAS version and more details like operating system used
    - list all programs that are being submitted and briefly describe their purpose
      - Also detail if and which macros are used by each program
    - Separately list out all macros utilized and describe their functionality

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