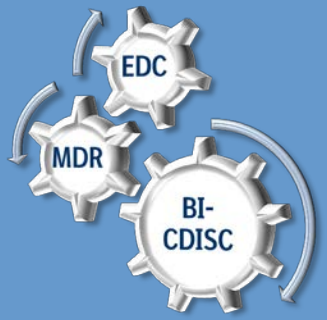
CDISC GS User Group Meeting

eCTD Consultation Meeting with PMDA



14 February 2017

Boehringer Ingelheim

Transition Period - Hybrid Submission
eCTD Consultation Meeting with PMDA in Q4 2016

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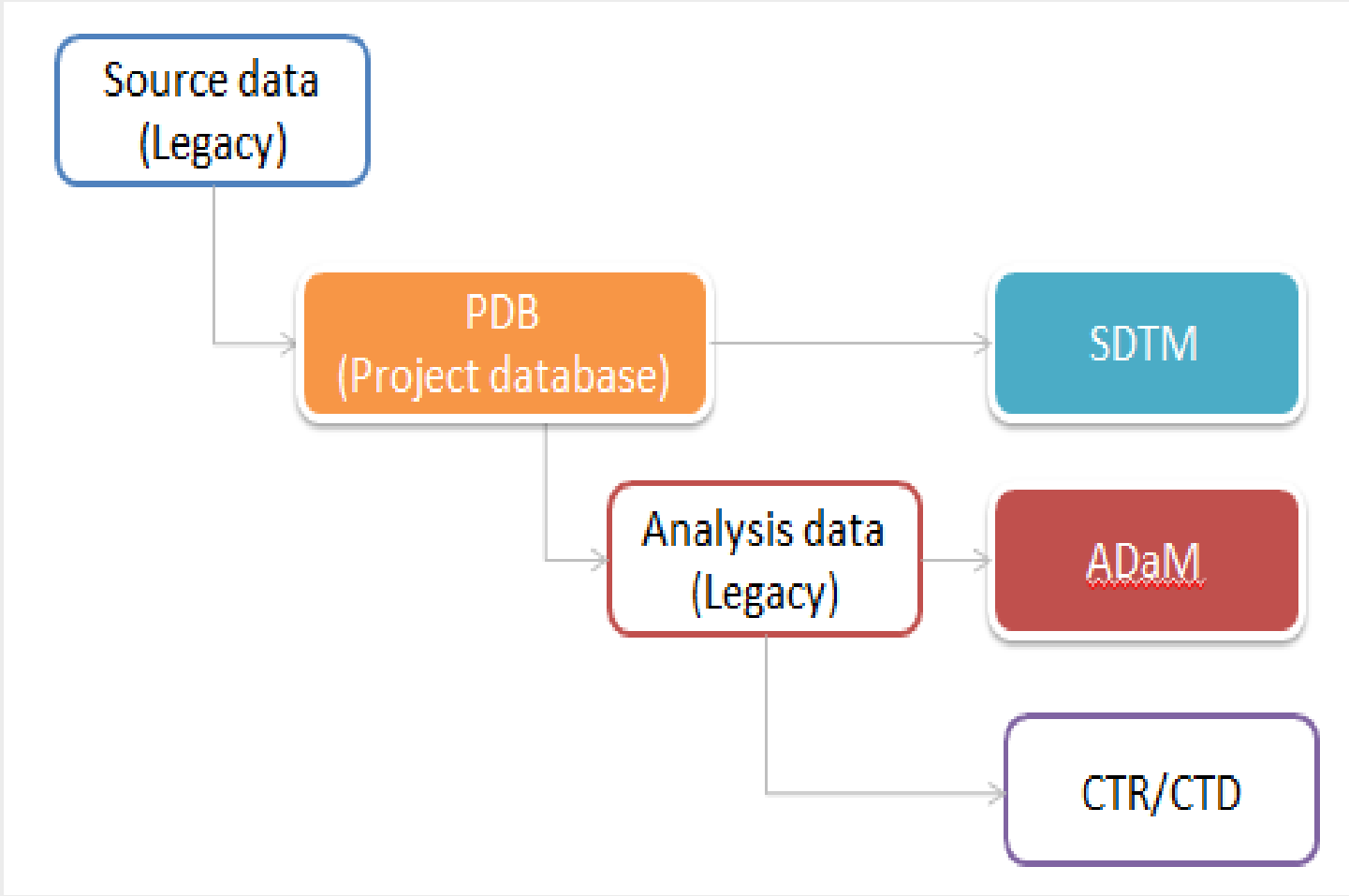

Questions and Answers 1

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Topic	Subtopic	Comment
Lessons learned	**General questions**	There is limited time available within an eCTD consultation meeting. Therefore DO NOT ask GENERAL questions. Stick with questions directly related to your submission
ARM		Just a briefing document (ppt converted to PDF) is not sufficient. ARM is needed.
File size 5 GB	**If violated**	If a file larger than 5 GB exists, do not split. Instead communicate with the PMDA so that they can prepare the environment. Inform teams as soon as possible in the process.
eCTD	**Data updates**	Study requires a later update after final DBL. Overwrite previous data files. Do not change names

Questions and Answers 2

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Topic	Subtopic	Comment
Communication	**Feed-back on confor-mance**	Paper documents will be used by PMDA and sent to the sponsor.
	Contact person	Point of contact will be nominated from the Office of New Drug I General topics (e.g. application of PMDA data consultation meeting)
	Help desk	Only for topics related to Gateway. Email with questions attached using PMDA template.
	Fax process	Very general questions on a submission only (not related to eData aspects) to PMDA, eg regarding applications / processes FAX to be sent to the Office of Review Administration

Questions and Answers 3

Topic	Subtopic	Comment
SI Units		Not fully clarified, in general the tendency to request SI was confirmed **Recommendation: in case of uncertainty as part of eCTD consultation confirm unit mapping sheet with PMDA** orresu --> stresu, mmHG --> pa, .../L --> L is ok, .../kg --> .../g
PMDA environment	**Conformance validation**	Validation rules + explanation on finding categories along with their implications sufficient for validation? Nothing else is needed, also not from Pinnacle21 Enterprise version PMDA doesn't recommend to Pharma for using a specific software. Therefore no functionalities can be recommended. PMDA only uses PMDA validation rule which is posted on PMDA homepage

Questions and Answers 4

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Topic	Subtopic	Comment
SDTM	**--BLFL**	No full consistency SDTM with ADaM needed.
	EPOCH	EPOCH is of course needed, should be filled as good as possible, but blanks are acceptable.
	AETRTEM	If collected on the eCRF it has to be submitted otherwise it is not mandatory. But PMDA reviewers are highly interested to see it in the pilots running. Clarify ambiguities resulting in potential blanks in the SDRG.
	Primary Endpoint related data in SUPP-- domains	Considered a general question which we are asked to unerstand cannot be answered in an eCTD consultation meeting. **NOTE: raise awareness about this specification and expectation (no endpoint related information in SUPP domains). If such a scenario occurs, communicate to PMDA as early as possible.**