Reduce Queries from Regulatory Authorities

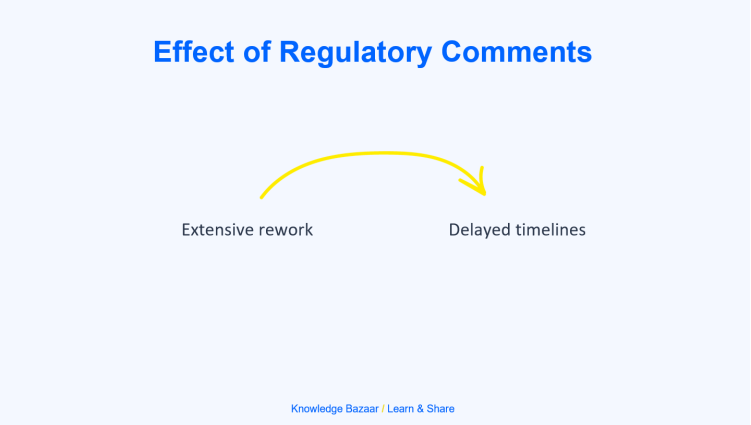
Discussions during the Knowledge Bazaar at PHUSE US Connect 2023

Discussion highlights:

👉 Direct contact between the programmers and regulatory authorities will be beneficial

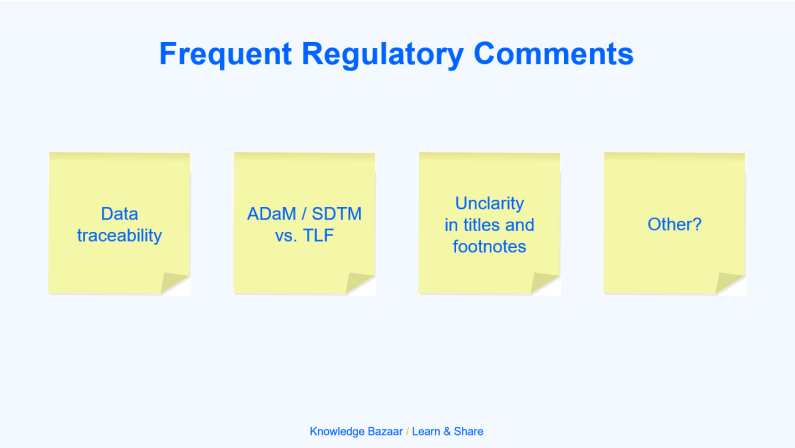
👉 Traceability requirements are not always clear for the programming department

👉 Variation between regulatory reviewers within the same agency creates variability in queries



With the increasing complexity of clinical trials and the growing number of different data sources used for evaluating these trials, we probably will get a higher number of regulatory information requests based on the data and output we submitted.

During the discussions at the Knowledge Bazaar, we identified that as clinical and statistical programming departments, we would like to have more direct contact with the regulatory reviewers. Then we can better explain and align with them on the needs they have. Due to the siloed approach in clinical research, this is difficult nowadays. Both from the industry and FDA we need a change to enable more smooth and higher quality submissions.



During the discussions, we identified some more frequent experienced information requests like:

- Required variable missing
- Non-required variable missing
- Reference variable empty

The group additionally identified one more related issue on the extensible code lists. Some pharma companies think they can add unlimited extensions for all variations of a result, while the extensions are only to be added in case the original value cannot be mapped to an existing standard code.

There seems to be a mismatch between the CDISC standard required variables and the variables that the FDA expects. Although, as we discussed, this relates to the data traceability requirements of the FDA, it is not always clear to the programming department what is needed to show this traceability.

On the other hand, there seems to be a big variation between regulatory reviewers. Some know the CDISC standards quite well, some do not. The latter group often has a lot more questions about the data submitted.

We thank all the participants for their contribution.

Please contact us if you have any additional questions, or comments or like to learn more about our product.

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