# CTEP Proposal – Samvit Section 5.4.1.4

## 5.4.1 Data Repositories/Warehouse

4. Proactively work with CTEP leadership and system leads, as directed by COR to develop

best practices, generate data strategies, build data flows, and develop

### conceptual/logical/physical enterprise data models.

DIFZ/Samvit team members have been working at the NCI for over 21 years and providing system analysis, modeling and data standards development support in clinical research domain for various projects over the years. Although majority of the work has been at NCI CBIIT more recently, but in the earlier years it involved working closely with the CTEP staff and other NCI contractors in building detail data flows, process flows, data models and requirements elicitation tasks for the CTEP-ESYS, CTEP-CTSU and DCP-DESK systems. Some of the team members were part of the original CTEP-ESYS and DCP-DESK design team for building the conceptual, logical and physical data models and maintaining the model artifacts. Following are some examples of projects where Samvit has designed data models, developed best practices and process flows:

1. Over the last 10 years at NCI CBIIT, the Samvit team has led the development of the Biomedical Research Domains Group ([BRIDG](https://bridgmodel.nci.nih.gov/)) model. We are the modeling team of BRIDG and funded by NCI CBIIT as well as CDISC and FDA in the past. BRIDG model is an [ISO standard](https://www.iso.org/standard/66767.html) for representing clinical research and has been adopted by HL7 and CDISC as their domain information model. The model itself is a hybrid of conceptual and logical model. The logical aspects of the BRIDG model were driven by the extensive harmonization of the CDISC SDTM and CDASH standards and representing these implementation specific data structures in BRIDG. Samvit team has worked closely with CDISC SDTM and CDASH experts and have developed expertise in both these CDISC standards. The BRIDG model has been implemented in many large academic and commercial settings by starting with the use case specific parts of the BRIDG model and then driving the design of logical and physical models. Samvit team have been consultants to a large pharmaceutical CRO implementation of the BRIDG model where we developed best practices for building physical data models from BRIDG. Samvit has also participated in other Pharmaceutical company BRIDG implementation and provided consulting expertise. Due to the detail mappings of BRIDG to CDISC SDTM and CDASH domains and variables, BRIDG model continues to be of high interest for entities that have the requirement to submit CDISC SDTM data sets to the FDA. They leverage the relevant parts of the BRIDG model and drill down to design their clinical trial enterprise data repositories based on that.
2. Samvit team members were also the first analyst and modeling team for the NCI CBIIT Clinical Trials Reporting Program (CTRP). We were responsible for designing the conceptual, logical and physical model for CTRP. Samvit team also documented all the use cases and data flows between CTRP, CTEP-ESYS and CTSU systems. Samvit team successfully delivered the first version of the CTRP where the team worked closely with the CTEP-ESYS -Person and Organization model to support seamless data exchange of the clinical trial sites and the principal investigators associated with the trial to be registered at clinicaltrials.gov. Samvit team also designed and implemented the CTRP Data Warehouse in support of Data Table 4 and other CTRP reporting requirements.
3. In addition to NCI work, Samvit is currently working at the FDA developing data standards in drug development and drug quality domain and building the first ever structured data standards and representing them in a conceptual and logical data models.

DIFZ team proposes to bring our extensive knowledge in clinical research, and proven skills in analysis and modeling expertise to the CTEP initiative and work with the leadership to build and deliver the highest quality analysis and design artifacts that leverage industry standards and tooling to support the research focused objectives of CTEP.

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