# CTEP Proposal – Samvit Section 5.4.2.1

## 5.4.2 System Integrity and Interoperability

1. Collaborate with other NCI Contractors and grantees to enhance and/or expand

CTEP-ESYS integration with other systems within and/or outside the NIH perimeter

### firewalls to include, but not limited to:

1. NCI systems: The CTEP-ESYS shall interface and allow 2-way sharing of selected

information, as needed, with other NCI-owned systems including, but not limited to,

CTSU-Enterprise System (CTSU-ESYS), DCP’s Protocol Information Office

Clinical Trials System (PIO-CTS), Medidata Rave, Clinical Trials Reporting

Program (CTRP), and the Central Institutional Review Board (CIRB) application

suite.

1. Other systems: e.g., Clinicaltrials.gov; LPO clinical trial applications

Samvit was involved in the development of the Clinical Trials Reporting Program (CTRP) at NCI CBIIT since its inception in 2007 and until 2018. Samvit successfully led the technical and business analysis efforts to include requirements analysis and data modeling in support of all CTRP modules to include Trial Registration, Patient Accruals, Protocol Abstraction (PA), Person and Organization (PO), and CTRP Data warehouse reporting including Data Table 4 reporting. Samvit was also responsible for building CTRP’s data model and data warehouse.

Our responsibility as lead analysts included soliciting, documenting, and verifying all system interfaces and integration points between CTRP and internal and external systems. We worked closely and effectively with all CTRP stakeholders within NCI and outside to include federal and contracting staff. Our interactions included working with stakeholders from CTEP ESYS and ECM, DCP, CTSU-RSS, NCI’s EVS, NCI Grants, NLM's ClinicalTrials.gov, and commercial Clinical Trials Managements Systems (CTMSs) vendors and others. In addition to soliciting and documenting the requirements for each integration point, our team was responsible for relaying the requirements to the development team to ensure the correct understanding. Finally, our team lead the validation of the implementation of the interface with each the target systems. We worked closely with the contractor responsible for each target system to ensure data exchange was done accurately and in a timely manner with CTRP.

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