

CTSU Enterprise Applications

1. Introduction

The CTSU Enterprise system is a suite of integrated databases, applications, websites, and capabilities that support the CTSU activities and operations. These activities range from protocol development support, regulatory document processing, patient enrollment, data collection and quality assurance, data distribution, education, training, and service support through a CTSU Help Desk. The main applications that comprise the CTSU Enterprise are the Regulatory Support System (RSS), CTSU Website, Oncology Patient Enrollment Network (OPEN), Real Time Data Transfer System (RDTS), CTSU Enterprise Web Services (CEWS), Clinical Data and Regulatory Image Management Systems (CDIMS and RIMS), Financial Management Systems (FMS), Clinical Data Transfer System (CDTS), Oracle Clinical (OC), OC-Remote Data Capture (RDC), Medidata Rave and iMedidata. Medidata Rave and iMedidata are hosted applications. The enterprise system also includes event notifications through email, and scheduled data transfers via file transfer protocols (ftp). Most of these applications are custom, multi-tiered, web-based applications or websites and support data entry and data query, as well as report generation and data downloads.

The CTSU Enterprise applications are integrated via a common CTSU database. The integrations between the CTSU Enterprise and the external applications such as Cooperative Group systems and Medidata Rave have evolved over time to support various needs of the NCI CTEP, the ten Cooperative Groups, and other NCI CTEP-sponsored organizations such as the Phase 2 Cancer Consortia. The integrations are implemented with a loosely coupled architecture that integrates the systems and databases using a mostly transaction based approach over the Internet. In a loosely coupled architecture the component systems have no direct control, knowledge of behavior, or dependency on the other systems. This architecture provides the flexibility to interconnect these systems, while minimizing the impact of changes in any one system. This document provides the list of the applications within the CTSU Enterprise System along with a brief description of each system. In addition, details about existing and ongoing integration of the CTSU Enterprise with other systems are provided.

2. CTSU Applications Overview

The CTSU integrated view (see attached diagram) provides a pictorial view of the CTSU Enterprise system and its applications. All of the enterprise applications are shown around the circle surrounding the Enterprise Database (CTSU) and the Clinical Database (CDB). The CTSU Enterprise Database supports most of the critical applications in some capacity, while the CDB supports Oracle Clinical, RDC and Rave/iMedidata. A brief description of the CTSU Enterprise system applications is provided below.

2.1 Regulatory Support System (RSS)

The Regulatory Support System (RSS) includes a comprehensive store of IRB approvals, site registrations, and institutional and person credentials. Its primary goal is to reduce the redundant collection of regulatory, person and institutional data, and provide a mechanism to share pertinent information across the Cooperative Groups, NCI-supported networks, CTSU, and NCI CTEP. The Cooperative Groups, CTSU, and select networks also use RSS to enter and maintain relevant protocol and roster data. The system supports the patient enrollment process by managing the availability of protocols to sites based on the regulatory data collected, Group and network roster information, and the current NCI maintained status of investigators and sites. The supporting system architecture includes web-based Oracle Forms-based data entry screens as a front-end to the CTSU Enterprise Database, which is integrated with data from the CTEP Enterprise System, and an integrated and distributed document management system based on the Oracle I/PM and FAXCOM products.

2.2 Oncology Patient Enrollment Network (OPEN)

The Oncology Patient Enrollment Network (OPEN) is a web-based registration system for the enrollment of patients onto NCI-sponsored Cooperative Group and other select NCI-sponsored clinical trials. This system was developed to leverage the existing CTSU Enterprise system for regulatory and roster information and the existing integration of the CTEP Enterprise and Cooperative Group management systems. OPEN uses a multi-tiered distributed application model built on the J2EE platform. It uses the “Spring” open source application framework and the “Hibernate” open source data access framework.

2.3 Financial Management System (FMS)

The Financial Management System (FMS) creates and processes invoices in support of CTSU operations and patient accruals. This system does not perform any actual accounting functions, but interfaces with Westat’s CostPoint system for generating payment checks and performing reconciliation.

FMS is also an Oracle forms-based application and shares components (screens) with the RSS application, and uses the CTSU Enterprise Database as the backend.

2.4 CTSU Website

The CTSU website (<https://www.ctsuo.org>) has two areas – a public area and a member’s area. The public area of the CTSU website provides general information about the CTSU to physicians, patients and the general public. The member’s area of the CTSU website is designed to provide full support for members who wish to enroll patients on CTSU menu trials. Members also have access to a subset of data from the RSS based on their membership credentials maintained by the CTSU, Cooperative Groups, and networks. .

The CTSU website is a .NET based application and uses the CTSU Enterprise Database (Oracle) as the backend.

2.5 Image Management Systems (IMS)

The Regulatory Image Management System (RIMS) and the Clinical Data Image Management System (CDIMS) are used by CTSU operational staff to eliminate the use of paper in capturing the required regulatory and clinical data. Site users across the country fax or e-mail regulatory and clinical documents to CTSU fax servers that capture the document images; the images are processed using a workflow data entry system. The IMS is suite of applications comprised of COTS software (such as Faxcom, Quillix, Oracle Clinical, Oracle I/PM) and Westat developed software which was integrated seamlessly by the CTSU team.

2.6 Clinical Data Transfer System (CDTS)

Clinical data is transferred to the Groups via files of data extracted from Oracle Clinical into XML format based on the NCI's Common Data Elements (CDEs). The CDTS is a Java based application that is integrated with Oracle Clinical and constructs the CDISC ODM (Clinical Data Interchange Standards Consortium Operational Data Model) based XML document for each of the clinical Case Report Forms (CRF) received at CTSU.

2.7 Read Time Data Transfer System (RDTS)

The Real Time Data Transfer System (RDTS) is a java application that supports subscription-based XML transactions. Whenever data is updated in the CTSU Enterprise Database via any mechanism (e.g., using an RSS screen such as a person roster screen or IRB approval screen, nightly jobs, or transactions processed from the CTEP Enterprise), RDTS transactions are triggered and sent to the subscribing systems. There are twenty eight (28) RDTS transaction types, a few of which are deprecated. Cooperative Groups have the ability to subscribe and process only the transactions that they need. Some Cooperative Groups subscribed to and process most of the transaction types and have become fully integrated with RSS, while other Cooperative Groups subscribed to many transaction types, but process specifically filtered transactions based on attribute values.

2.8 CTSU Enterprise Web Services (CEWS)

The CTSU Enterprise Web Services (CEWS) is a collection of services that provide access to data from the CTSU Enterprise system. CEWS is a demand based (pull) system where data is provided when the user (web service consumer) requests the data. CEWS consists of a generic XML request based web service and business process specific web services. Among other capabilities, the business process specific web services provide several features such as claiming a person based on the CTEP ID or assigned role for a person. CEWS also includes access to a CTEP Identify and Access Management (IAM) authentication service used to authenticate the users against the CTEP IAM system.

2.9 CTSU Enterprise Network Transaction Engine for Rave (CENTER)

The CTSU Enterprise Network Transaction Engine for Rave (CENTER) is a multi-threaded java application supporting multiple sources and multiple targets for the different transactions. The spawning of transactions to subscribed targets occurs within CENTER. Currently CENTER supports RSS, OPEN, and the CTSU website as transaction sources and iMedidata and Rave as the transaction targets. CENTER has capabilities for transaction management, notification management, error management, recovery, and URL resolution.

2.10 Help- Desk Management

The CTSU Help Desk shall have an internet based management system to support ticket entry, issue tracking, and reporting capabilities.

2.11 Oracle Clinical (OC) and Oracle Clinical Remote Data Capture (RDC)

Oracle Clinical (OC) is a clinical data management system that provides full clinical database management support. Oracle Clinical enables management of all clinical trial data in a single system, improving accuracy, visibility, and data integrity. RDC is a web front end to OC that provides electronic data capture and clinical data management capabilities. At CTSU, OC and RDC have been used for clinical trial data management for select studies. The NCI has now adopted Medidata Rave® as its multi-center RDC.

