

Introduction

Achieving excellence in clinical research at USC requires a supporting infrastructure. This need is evident in operational expectations from our faculty, federal regulatory agencies, NIH, pharma sponsors, USC strategy, USC Norris Comprehensive Cancer Center, Keck Medical Center of USC, and many other stakeholders of our school, including our patients.

A Clinical Trials Management System (CTMS) will significantly improve our ability to operationalize high quality clinical research in a compliant fashion.

As we grow, the decision support and enterprise management capability of our current infrastructure is hindered by:

- Decentralized activity throughout the institution
- Difficulty identifying potential research participants
- Difficulty identifying established research participants throughout their course of treatment/participation
- Challenge of adequately budgeting and tracking actual costs
- Separating billable versus non-billable of the research
- Managing human subjects documentation requirements
- Understanding the research activity/volume at a departmental and institutional level
- Collecting and managing data in a consistent way for analysis
- Tracking the status of sponsor invoices and payments received across the enterprise
- Fulfilling the data needs of our affiliated study sites (e.g. CHLA, LAC, etc.)
- Ensuring full recovery of all reimbursable costs
- Ability to review (minimal) data on patients in order to optimize planning of future studies or to support applications for funding for research

A CTMS becomes a central repository for study-related information. This will make the information easier to access for data analysis and for collaboration with other institutions, thereby facilitating multi-site studies under the direction of USC Principal Investigators.

University Demographics

The University of Southern California (USC) is a private, not-for-profit institution of higher education located in Los Angeles, California. USC educates students, conducts research, cares for patients, offers artistic and athletic programs and provides outreach programs for the community. USC's strategic vision emphasizes "scholarship with consequence," and aims to provide translational research for societal benefit.

USC's academic organization includes the USC Dana and David Dornsife College of Letters, Arts and Sciences and 18 professional and artistic schools. The medical (1885) and pharmacy (1905)

schools are the first and oldest in Southern California. Biomedical research occurs in these schools, along with the Ostrow School of Dentistry, Viterbi School of Engineering, David Dornsife College of Letters, Arts and Sciences and Davis School of Gerontology. In addition, USC is the largest private employer in the City of Los Angeles. There are currently over 38,000 students, 3,400 full time faculty, and 11,800 staff comprising the USC Trojan family.

Clinical care is provided through Keck Medical Center of USC, along with our affiliates Children's Hospital of Los Angeles (CHLA, an independent non-profit) and LAC+USC Medical Center (owned by the County of Los Angeles). Physicians at these hospitals, many of whom are engaged in clinical research, are predominantly USC faculty. Clinical research at LAC+USC, along with Keck Medical Center, is administered jointly by USC and LAC+USC under a combined IRB, whereas research at CHLA is administered separately by CHLA.

Support for clinical research is offered by the Norris Comprehensive Cancer Center along with the Clinical and Translational Science Institute (CTSI). Support for cancer studies is centralized and standardized within the Norris Comprehensive Cancer Center. Investigators working on other diseases have varying levels of support, tending to be much more decentralized.

The university has an annual budget of more than \$3 billion dollars, with over \$600 million in annual research expenditures. USC is governed by a Board of Trustees and led by President C. L. Max Nikias in conjunction with a senior administrative team responsible for managing institutional operations through administrative units and schools.

Current Environment

USC is in the midst of installing a collection of new systems to support research administration, under the leadership of the Information Technology Services (ITS) office. The TARA project ("total access for research administration") will provide tools for budget generation, workflow management, financial forecasting, account set-up, research core accounting and billing, business intelligence, and regulatory review (IRB, IACUC, conflict of interest, radiation safety, biological safety) within an integrated environment. Relying on Quali Coeus, Click Commerce and other platforms, these tools will integrate with the university's new Quali Financial System for account management.

USC, is also in the midst of installing the Cerner electronic health record system for Keck Medical Center, under the leadership of the Health Systems Chief Information Officer. CHLA is also installing a Cerner system in the near future, and LAC+USC is expected to install Cerner in the future. We also expect to create a research data warehouse from the electronic health record and provide tools for researcher access, integrating across all three institutions.

USC does not yet have an integrated solution to support enterprise-wide needs of those conducting clinical research. At present, the Cancer Center Informatics team and Clinical

USC CTMS Project (Project Summary and Business Specifications)

Research Office provide limited systems to support and manage data in particular areas of the clinical research enterprise (e.g. CAFE, IRIS, & TRUE).

USC has significant resources to support software installations. IT support is provided in these places:

- Research financial systems (Kuali): information technology systems
- Research regulatory system (Click Commerce): office of research
- Electronic Medical Records (Cerner): Keck Medical Center CIO
- Industry sponsored clinical research (IRIS, TRUE): USC Clinical Research Organization
- Data management for cancer trials (CAFE): Norris Cancer Center

In addition, USC is home to a major high performance computing center, and conducts more computer science research than any other American university. Therefore, we offer a sophisticated knowledge base for installing innovative software systems.

Compliance

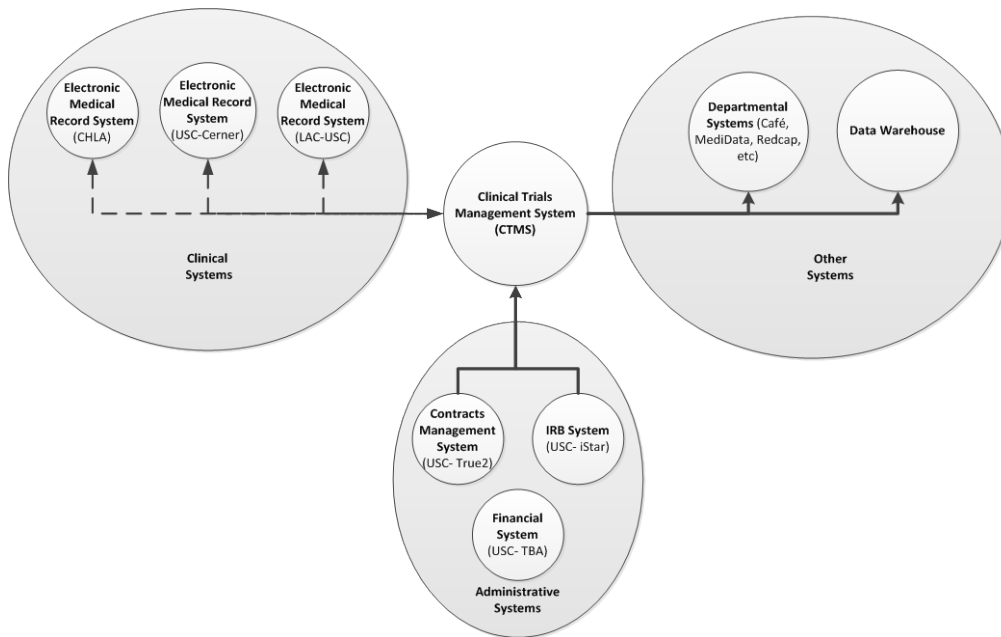
The complexities faced by the Clinical Research Enterprise at USC have increased significantly in the last several years. Most notable of these drivers may be the billing compliance exposure that many institutions are now trying to mitigate. Since the 9/19/2000 National Coverage Decision to permit the billing of certain research charges to Medicare, some academic medical centers have been slow to adapt their business processes accordingly. Investigation into the double-billing of charges remains on the OIG work plan. This has yielded a variety of high-profile, multi-million dollar fines and settlements at numerous institutions across the country.

To address this problem, USC instituted a billing compliance program to ensure Medicare Coverage Analysis and consistency checks in pre-award, and billing compliance in post-award. USC seeks to simplify and expedite these processes through the acquisition of a CTMS.

Future Environment

The intent is the purchase and installation of an enterprise-wide system to support clinical research at USC, with the goal of having timely up-to-date clinical research and financial information available to all Departments/Divisions/Centers. The new enterprise-wide system will both replace existing systems where possible, and add functionality that is not currently present, as represented by the business requirements specified later in this document.

USC CTMS Project (Project Summary and Business Specifications)

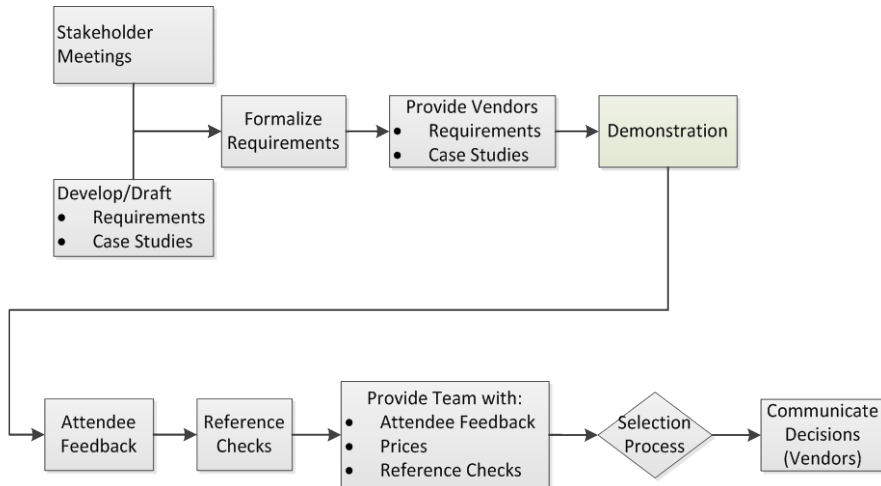


Selection Process:

It is the intention of USC to seek and analyze CTMS applications that would satisfy the enterprise requirements. The selection process will seek input from major stakeholders (e.g. Hospital Administration, Finance, Regulatory, Cancer Center Informatics, CTSI, Study Coordinators, Biostatistics, Principal Investigators, Clinical Systems IT, CHLA & LAC+USC, & Clinical Research Business Operations, USC Clinical Research Organization). The final selection will be made by the (USC Research Executive Leadership Team).

Comment [EP1]: Made this statement generic, until we can identify the key folks that will make the final decision.

USC CTMS Project (Project Summary and Business Specifications)



Selection Criterion:

We will preferentially value the following in the selection process:

- Ability of product to meet the business requirements in each of the areas specified later
- Ease of integration with other systems at USC, including Cerner, ClickCommerce, Quali Coeus, Quali Financial System and other Lawson.
- Flexibility of product to be adapted or customized to changing needs over time, and the variety of needs that exist within the university, while still achieving needed standardization.
- Reporting tools and data extraction (e.g. NCI, NIH, etc.)
- Vendor Support and User Community
- Ability to submit data electronically to external systems (e.g. ClinicalTrials.gov, CTRP (Clinical Trials Reporting Protocol), Medwatch, Adeers (Adverse Event Expedited Reporting System)).
- Experience with Academic Medical Centers with a similar research activity and governance structure, along with references provided from these prior installations.
- Likelihood to achieve specific deliverables and timeframes
- Total cost of ownership over a 15 year lifetime.

Proposal Format

Comment [EP2]: Working with Purchasing to get the format

Appendix A: Business Requirements

Requirement	Description
<p>Study Management</p>	<ul style="list-style-type: none"> • The application needs to Support: <ul style="list-style-type: none"> ○ Study Setup and Tracking (S1) - (e.g. study status timeline, capture information with regards to IRB) ○ Multi Center Studies (S2) (e.g. multiple enrollment sites, enable internal/external study management) ○ Study Status Controls (S3) – these controls are intended to enable business rules triggered upon specific study statuses (e.g. prohibit entry of new patients based on IRB status, etc. ○ Study Level Identifiers (S4)– these identifiers are intended for tracking/monitoring and reporting <ul style="list-style-type: none"> ▪ School/Department/Division ▪ Core Service Locations (e.g. CTU, Pharmacy, Radiology, Hospital, Clinics, etc.) ▪ Enrollment Sites (e.g. CHLA, Norris, Keck, LAC, etc.) ▪ Funding Type & Funding Agency ▪ Study Team (e.g. PI, Co-Investigator, Study Coordinator, CISO Staff for Norris Comprehensive Cancer Center studies, Biostatistician, Administrator, etc.) ▪ Study Identifiers (e.g. IRB number, IND/IDE Number, NCT Number, CISO Number, Project Number, Grant Number, Account Number, Radiology Number, SWOG Number, Sponsor Protocol number, etc.) ○ Study Team Management (S5) – to add/modify/remove study level access rights for the study Team members in order to reflect their respective roles within the study ○ Study Status (S6) - to support multiple study statuses as it relates to the particular studies timeline. The study statuses should accommodate the various requirements (e.g. IRB Statuses, Contract/Administrative Statuses, and Core facility study statuses)
<p>Patient Management</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • Patient Enrollment & Management (P1) – To provide tools to enable the study team to enter/associate the patient to a study by utilizing an enterprise EMPI (Enterprise Master Patient Index). In addition there will be cases that would require a manual method of patient entry & study association. • Patient Identifiers (P2) - There needs to be multiple patient identifiers that are associated to a master patient identifier to enables appropriate identification of patients through ough the application. This is especially

	<p>important when there are information exchanges between upstream or downstream interfaces (e.g. Electronic Medical Record, Laboratory, and Billing Systems). There needs to be at least 5 unique patient identifiers</p> <ul style="list-style-type: none"> ○ Master Patient Identifier ○ USC-MRN ○ LAC+USC-MRN ○ LA County Master Patient Identifier ○ CHLA-MRN ○ Patient Study ID <ul style="list-style-type: none"> ● Demographic Information (P3) –The demographic information should be kept synchronized with the appropriate data sources (e.g. Electronic Medical Records). There are a set of standard fields that are required in order to support clinical trials operations and federal reporting requirements. Some of the fields include: <ul style="list-style-type: none"> ○ Name & Alias ○ Race & Ethnicity ○ Date of Birth / Date of Death ○ Place of Birth ○ Address, Zip Code, Telephone, & Email ○ Type of insurance ○ Emergency Contact Information ● Concomitant Medications (P4) – The patients’ concomitant medications should be kept synchronized with the appropriate data sources (e.g. Electronic Medical Records). Additionally, the application should accommodate situations where data is to be managed manually. ● Medical History (P5) – The patients’ primary, secondary diagnosis, family history, and respective procedures should be synchronized with the appropriate data sources (e.g. Electronic Medical Records). Additionally the application should accommodate situations where data is to be managed manually. ● Patient Laboratory Results (P6) – The patients Laboratory Results should be kept synchronized with the appropriate data sources (e.g. Electronic Medical Records). Additionally, the application should accommodate situations where data is to be managed manually. ● Protocol Specific Calendars (P7) – The patients should be managed using protocol specific calendars that capture the visits and tasks that are required as per the protocol design. The calendars need to calculate future visits based on the patients date of enrollment. In addition if there are amendments which require changes within the protocol calendar there needs to be functionality to accommodate accordingly. ● Adverse Event Tracking (P8) – The patients adverse events (e.g. AE and SAE) need to be recorded and monitored to comply to federal, institutional, and protocol reporting requirements (e.g. Med Watch, IRB, NCI, etc.) ● Multiple Protocols Tracking (P9) – The end users who are providing care
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	<p>to the patients need to understand if the patients are on multiple protocols. In addition if they are participating on multiple studies where the treatments conflict.</p> <ul style="list-style-type: none"> • Patient Randomization (P10) – The application should have the ability to randomize subjects for internally initiated studies, based on the requirements from the protocol and the study design • Printing (P11) – The application needs to provide functionality to print patient schedules and case report forms as needed to support various ancillary activities (e.g. Provide patient future visits, Support Invoicing, Support Audits, etc.). Upon printing the application is to watermark the documents with the protocol number, date, time, Patient Study ID, and there should be no PHI.
<p>Financial Management</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • Study Budgeting (F1) – The application is to provide functionality to build study budgets so as to facilitate the administrative operations <ul style="list-style-type: none"> ○ Calendared (e.g. Visits, Procedures (Coded and Non-Coded) ○ Non-Calendared (e.g. IRB Startup, Pharmacy Startup, Monitoring, etc.) ○ Multiple Charge masters per budget (e.g. LAC+USC, CHLA, Keck Hospital, Norris Hospital, CTU, etc.) ○ Labor Costs (e.g. Labor Rates, Fringe, etc.) ○ Other Costs (e.g. Overhead, Tithing, etc.) ○ Costs must be categorized into Fixed and Variable ○ Calculations take into consideration input factors (e.g. Patient Enrollment, Patient Protocol Completion, etc.) • Charge masters (F2) – There are studies conducted within multiple institutions. In these cases there is a need to support multiple charge masters. The application needs to have multiple charge masters. In addition the fields within the charge master must take into consideration the following <ul style="list-style-type: none"> ○ Location ○ Resources ○ Cost (Professional and/or Technical) ○ Description ○ CPT Code • Medicare Coverage Analysis (F3) – The Medicare Coverage Analysis (MCA) needs to be created simultaneously with the protocol calendar. In addition there needs to be a location to document coverage determinations and any respective references (e.g. links, documents, etc.). • Milestone Management (F4) – The application needs to facilitate a variety of milestones as per the contract terms. The milestone setup should accommodate frequency, limit, and costs. There are a variety of milestone types that are embedded within a contract that need to be managed, namely:

	<ul style="list-style-type: none"> ○ Visit level ○ Task/Event Level ○ Study Status Level ○ Patient Status Level ○ Adverse Events ○ Ad hoc <ul style="list-style-type: none"> ● Invoice Management External (F5) - The application needs to facilitate a variety of contract templates as per the contract terms. The invoice module needs to accommodate the invoicing for particular date ranges, in addition to including/excluding particular achieved milestones as needed. There needs to be standard fields (e.g. Payee Contact Information, Payer Contact Information, Account Number, Study Number, IRB Number, Sponsor Protocol Number, No-PHI, Milestone Description, and Patient Study ID). ● Invoice Management Internal (F6) - The invoice module needs to accommodate the invoicing for particular date ranges, in addition to including/excluding particular achieved milestones as needed. There needs to be standard fields (e.g. Payee Contact Information, Payer Contact Information, Account Number, Study Number, IRB Number, Sponsor Protocol Number, No-PHI, Milestone Description, and Patient Study ID). ● Study Revenue Cycle (F7) – The application needs to provide functionality to post payments against an invoice/study. In addition to reconcile payment against expense wherever applicable. There needs to be a continual management of Accounts Payable and Accounts Receivable until the end of the contract/study. ● Library (F8) – The application needs to provide a library for the budgets, charge masters, calendars, and Medicare Coverage Analysis
<p>Data Management</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> ● Electronic Case Report Forms (D1) – To provide functionality to accommodate protocol specific data capture requirements. <ul style="list-style-type: none"> ○ Data Fields (e.g. Text, Radio Buttons, Dropdown, Date, Checkboxes, Lookups, etc.) ○ Inter & Intra Form Logic (e.g. disable, enable, copy, calculate, etc.) ○ Calculation (e.g. Summation, Multiplication, Division, etc.) ○ Standard Codes used for Electronic Case Report Form ○ Case Report form data maps ● Printing (D6) – The application needs to provide functionality to print patient schedules and case report forms as needed to support various ancillary activities (e.g. Provide patient future visits, Support Invoicing, Support Audits, etc.). Upon printing the application is to watermark the documents with the protocol number, date, time, Patient Study ID, and there should be no PHI. ● Data Reporting & Export Tools (D7) – The application needs to report on the electronic case report forms along with any other screens where data

	<p>is being captured. The data needs to be presented in a manner where the biostatistician can analyze the data set (e.g. data presented in the context of time and treatment outputs). The data needs to be exported into analytical and visualization tools (e.g. Excel, SASS, CSV, etc.)</p>
<p>Reporting</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • Standard/Canned Reports (R1) - The application needs to support a series of standard reports that a user's is able to run on a real-time basis within the application itself. The reports should be available in 4 levels <ul style="list-style-type: none"> ○ Study Level <ul style="list-style-type: none"> ▪ Portfolio Management (e.g. Reports by – Department/Division, Location, Funding Agency, PI, Study Team, etc.) ○ Patient Level <ul style="list-style-type: none"> ▪ Departmental/Investigator Accrual Reports ▪ DSMC Reports ▪ QAMC Reports ○ Financial Level <ul style="list-style-type: none"> ▪ Study Summary and Rollup Reporting (e.g. Department/Division, Location, Funding Agency, PI, Study Team, etc.) ▪ Comparison (e.g. year to year, expected vs. actual) ○ Administrative Level ○ Other <ul style="list-style-type: none"> ▪ NCI Reporting (Summary 3 and Summary 4) ▪ NCI Clinical Trials Reporting Program (CTRP) ▪ ClinicalTrials.gov • Custom Reports (R2) – The application needs to provide tools to create custom reports that are at multiple levels. • Statistical Report Extract (R3) - The application needs to report on the electronic case report forms along with any other screens where data is being captured. The data needs to be presented in a manner where the biostatistician can analyze the data set (e.g. data presented in the context of time and treatment outputs). The data needs to be exported into analytical and visualization tools (e.g. Excel, SASS, CSV, etc.) • Biorepository/Specimen Management (R4) – The application needs to provide tools for end uses to facilitate their respective operations (e.g. inventory management, sample discovery, billing)
<p>Security</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • Utilization of Active Directory (SE1) – the utilization of Active Directory provides a central location for network administration and security. • Access Rights (SE2) – The application should provide access rights globally and locally. In other words there should be application level access rights as well as study level access rights (e.g. Role Based). There also needs to

	<p>be administrative level rights that can be restricted by department/division and location.</p> <ul style="list-style-type: none"> Clinical Context Object Workgroup (CCOW) Compliant (SE3) - CCOW is the process of using particular "subjects" of interest (e.g., user, patient, clinical encounter, charge item, etc.) to 'virtually' link disparate applications so that the end-user sees them operate in a unified, cohesive way. This means that when a clinician signs onto one application within a CCOW environment, and selects a patient, that same sign-on is simultaneously executed on all other applications within the same environment, and the same patient is selected in all the applications, saving clinician time and improving efficiency.
<p>Biorepository/Specimen Management</p>	<p>Specimen Management Collection (BR1) – the application needs to be able to collect data related to a specimen, along with its respective products.</p> <ul style="list-style-type: none"> Specimens Collection Location from (USC Norris, LAC+USC, USC Keck) Method of Collection Who/When Collected Specimen Type/Description Protocol Informed Consent (e.g. consent tiers) Other Data include: <ul style="list-style-type: none"> Demographic Information (e.g. race, ethnicity, gender, etc.) Tumor Type and Characteristics (e.g. pathology report, etc.) Clinical Data (e.g. diagnostic, procedures, etc.) Linking to parent to children/by products (e.g. genomics, proteomics data) <p>Specimen Identifiers (BR2) - There are multiple identifiers that need to be associated to the specimens collected, so that there’s traceability throughout the lifecycle.</p> <ul style="list-style-type: none"> Specimen Number (TPN – Tissue Procurement Number) Surgical Pathology Accession Number Specimen ID Number – Ties back to the patients demographic data Medical Record Number and Patients Study ID Barcode Number and/or UUID (Universally Unique Identifier) – see table below for example of naming convention (Source: https://wiki.nci.nih.gov/display/TCGA/TCGA+Barcode) <p>Specimen Inventory Management (BR3) – The application needs to support specimen inventory management. There are multiple levels of storage that need to be tracked (e.g. Building, Room, Freezer, Shelf, Rack, etc.). The industry standard is to track the specimens using barcode technology.</p>

<p>Interfaces</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • Interface (IN1) – This is the USC Electronic Medical Record interface. <ul style="list-style-type: none"> ○ Demographics (Incoming to CTMS) ○ Diagnosis and Procedures (Incoming to CTMS) ○ Emergency Contact Information (Incoming to CTMS) ○ Concomitant Medications –Retail Module (Incoming to CTMS) ○ Concomitant Medications – Inpatient Module (Incoming to CTMS) ○ Laboratory Results (Incoming to CTMS) ○ Scheduling (Incoming to CTMS) ○ Signed Patient Informed Consent (Incoming to CTMS) • Interface (IN2) – This is the LAC+USC Electronic Medical Record interface <ul style="list-style-type: none"> ○ Demographics (Incoming to CTMS) ○ Diagnosis and Procedures (Incoming to CTMS) ○ Emergency Contact Information (Incoming to CTMS) ○ Concomitant Medications (Incoming to CTMS) ○ Laboratory Results (Incoming to CTMS) ○ Scheduling (Incoming to CTMS) ○ Signed Patient Informed Consent (Incoming to CTMS) • Interface (IN3) – This is the USC Quali Financial Services interface <ul style="list-style-type: none"> ○ Study Milestones Triggered (Outgoing from CTMS) ○ Invoices Sent to Sponsor (Outgoing/Incoming to CTMS) ○ Sponsor Payments (Outgoing/Incoming to CTMS) ○ Account Balance (Incoming to CTMS) • Interface (IN4) – This is the IRB system interface <ul style="list-style-type: none"> ○ Study Title (Incoming to CTMS) ○ Investigator & Study Team (Incoming to CTMS) ○ Enrollment/Recruitment Location(s) (Incoming to CTMS) ○ IRB Study Status(s) (Incoming to CTMS) ○ Link to approved blank Informed Consent (Incoming to CTMS) ○ Enrollment data reports and possible adverse events (Outgoing from CTMS) • Interface (IN5) – This is the Contracts Management system interface <ul style="list-style-type: none"> ○ Budget ○ Medicare Coverage Analysis ○ Research Order Form ○ Contracts Study Status ○ Sponsor/Funding Agency Information
<p>Compliance</p>	<p>The application needs to Support:</p> <ul style="list-style-type: none"> • 21 CFR Part 11 (C1) – The application needs to support the FDA guidelines, especially for studies where USC is the originator. <ul style="list-style-type: none"> ○ Secure Authentication ○ Electronic Signature ○ Audit Trails

	<ul style="list-style-type: none"> ○ Software Validation ○ Security (Global and Study level) ● HIPAA (C2) <ul style="list-style-type: none"> ○ Secure Authentication ○ Audit Trails ○ Security (Global and Study level) ● Good Clinical Practices (C3) – The application needs to support ICH E-6 Good Clinical Practices and its related requirements
Document Management	<p>The application needs to Support:</p> <ul style="list-style-type: none"> ● Study level documentation association (DM1) <ul style="list-style-type: none"> ○ Standard Operating Procedures ○ MCA ○ ROF ○ Budget ○ Drug Brochure ○ Imaging Manual ● Patient level documentation association (DM2) <ul style="list-style-type: none"> ○ Signed Informed Consent – this needs to inherit the study level security settings. The idea is that only authorized individuals can view this information. ○ Lab Results
Notifications	<p>The application needs to Support:</p> <ul style="list-style-type: none"> ● Logic Based Notifications (N1) –There needs to be multiple triggers based on particular conditions (e.g. Based on Study Status, Protocol Changes, Patient Enrollments) ● Notifications (N2) <ul style="list-style-type: none"> ○ Notifications need to be sent via email ○ Notifications need to be customizable (e.g. content & subject line) ○ Notifications should be setup based on role based rights
Connectivity	<ul style="list-style-type: none"> ● Web-Based (C1) – The application needs to be accessed through the internet. In addition it should be available on multiple browser platforms <ul style="list-style-type: none"> ○ Safari ○ Internet Explorer ○ Google Chrome ○ Firefox ● Mobile Devices (C2) – There are some aspects of the application that should be readily available through mobile devices. The trend to move to mobile technology is moving into the Healthcare settings <ul style="list-style-type: none"> ○ Tablet and/or iPad ○ Android and/or iPhone

<p>Workflow</p>	<ul style="list-style-type: none"> • Data Management Workflow (W1) – The application needs to facilitate a Data Management Workflow for studies where USC is managing the study and data management aspects • Generic Workflow (W2) – The application needs to facilitate a workflow where specific users can review/approve documents (e.g. Budgets, Medicare Coverage Analysis, CISO Workflow, CTU Workflow, Protocol Documents, etc.) • Evidence of Review (W3)– The application needs to support evidence of review from the Principal Investigator or qualified personnel for CRF’s, Lab, Radiology, Adverse Events, Protocol Violations,
<p>Users</p>	<ul style="list-style-type: none"> • Active Users (U1) – estimated 500 active users • Simultaneous Users (U2) – The application needs to support the demands of multiple users (≈100) performing a variety of functions simultaneously • User Accounts (U3) – the application needs to manage the following information per each user account (Name, Title, Department, Division, Email, Telephone, Employee ID, Address, Training (e.g. CTMS Date, HIPAA Date, CITI Date, etc.)
<p>Number of Studies</p>	<ul style="list-style-type: none"> • Estimated 600 ± 100 active studies with over 11,000 patients

Appendix B: Case Scenarios

Business Use Case		
Case	Category	Description
1	Study Management	Create a protocol and the various treatment arms
2	Study Management	Add multiple enrolling sites and their respective accruals
3	Study Management	Create a study calendar for each treatment arm.
4	Study Management	Track protocol through the various review committees (e.g. Protocol Review and Monitoring Process -PRMS)
5	Study Management	Track protocol timeline (e.g. IRB approval process, contract approval, hospital approval, etc.)
6	Study Management	Create Case Report Forms - CRF (e.g. toxicity, labs, SF-36, etc.)
7	Study Management	Capture multiple study identifiers (e.g. IRB number, IND/IDE Number, NCT Number, CISO Number, Project Number, Grant Number, Account Number, Radiology Number, SWOG Number, Sponsor Protocol number, etc.)
8	Study Management	Add a protocol violation
9	Financial Management	Create financial milestones (e.g. study level, patient level, and specimen level)
10	Financial Management	Create Medicare Coverage Analysis. Identify SOC and Study related procedures along with the respective citations and references.
11	Financial Management	Create a study budget (e.g. patient care costs, administrative costs, misc. costs, etc.)
12	Finance Management	Generate an invoice for triggered milestones (study level, patient level, and specimen level)
13	Finance Management	Post and reconcile sponsor payment to the study/invoice
14	Patient Management	Add new subject to protocol (USC patient and Non-USC patient)
15	Patient Management	Track eligibility and modify patients/subjects study status.
16	Patient Management	Attach the subject to a study calendar and enter data into CRF within a specific time point
17	Patient Management	Add an Adverse Event (AE) and Serious Adverse Event (SAE) to the subject.
18	Report & Data Management	Study Accrual reports

19	Report & Data Management	Protocol Violation and AE Summary reports.
20	Report & Data Management	Quality Assurance and Data Safety Monitoring reports
21	Report & Data Management	View protocol history
22	Report & Data Management	CTRP and Clinical Trials.Gov electronic reporting.
23	Report and Data Management	Reports for outstanding invoiced, accounts receivable, and accounts payable.
24	Biorepository Management	Set up specimen collection calendar
25	Biorepository Management	Add a specimen to patient
26	Biorepository Management	Split Specimen into various components
27	Biorepository Management	Track specimen quantity and storage location
28	Biorepository Management	Track specimen distribution
29	Biorepository Management	Track current availability.
30	Biorepository Management	Track Tissue Micro Array (TMA) creation.
31	Biorepository Management	Track specimen marker results.
32	Biorepository Management	Search for available specimens and their respective location and quantity by race, gender, diagnosis, etc.
Implementation Use Case		
Case	Category	Description
33	Compliance	Show audit trail (study level, patient level, data entry)
34	Data Management	Controls for data entry errors (e.g. Logic, Field Locks, etc.)
35	Data Management	Workflow for data management (e.g. data entry, query management, data correction, etc.)
36	Security	Create a new user and show role based security
37	Security	Make sure access can be assigned at a study level and users who do not have access to the study are not permitted to see the patients on that study

There are other topics to be discussed within the context of the demonstration which are namely: Implementation and deployment times, training, system performance, data migrations, interfaces (IRB, EMR, Other systems), and experience with HIPAA and FDA Audits.