

CTMS Standard Reports

To run a report, click the Reports screen tab, click the blue Report Name hyperlink, select filters, if needed, and then click Finish

Report Name	Synopsis	Prompts
Account Affiliations	<p>Data in this report includes, by Site, a listing of Account Affiliations (tracked on the Acct Affiliations View Tab).</p> <p>The output includes Protocol Name, Site Number, PI Name, Affiliated Account Name, Account Type, Account Role and IRB Approval Date (date is determined using the Document of IRB Approval Letter with the earliest Approved Status date; includes statuses of Approved by DCRI, Approved by IRB). In addition, address information for the Affiliated Account is included in the output.</p> <p><i>* If no filter is chosen, all sites will be included in the output whether data has been tracked or not. The report may be run to filter for only sites that have no data tracked, by selecting the blank check box (if available) on the Account Role filter screen.</i></p>	Protocol Site Status Region Account Role
CMP Visit Compliance Report	<p>A listing by Site of monitoring visits of the visit type Periodic Monitoring, Periodic Monitoring/Closeout or Closeout, indicating if the visit was performed within the Visit Window specified in the Clinical Monitoring Plan (CMP).</p> <p>Based on the following rules:</p> <ul style="list-style-type: none"> • Report is based on the Protocol specific CMP visit window (min/max in weeks) • The report will begin with the second visit that meets the rules for inclusion • CMP window is calculated on the time between Actual Completion Date of the previous visit and the Actual Start Date of the Subsequent visit • Includes only visits of the type of Periodic Monitoring, Periodic Monitoring/Closeout and Closeout • Monitor Name is determined from the Subsequent visit • If visit is within the window, the # Days Deviations will be zero • If visit is out of the window, too long, the # Days Deviation will be a positive number • If visit is out of the window, too short, the # Days Deviation will be a negative number • The % Compliant is calculated by dividing the number of visits within the Window by the total number of visits for the selected date range. • Unblinded visits are excluded from all calculations. 	Protocol Site Status Region Site Number Visit Date Range (Subsequent Visit Actual Start Date) Monitor

Report Name	Synopsis	Prompts
CMP Visit Planning Report	<p>A listing by Site of Periodic Monitoring Visits that are Planned but do not fall within the Visit Window specified in the Clinical Monitoring Plan (CMP).</p> <p>Based on the following rules:</p> <ul style="list-style-type: none"> • Report is based on the Protocol specific CMP visit window (min/max in weeks). • Visit window is based on Actual Visit Completion Date • Monitor Name is determined from the Submitted By field of the last completed visit • Includes only visits of the type of Periodic Monitoring (PMV) • Excludes visits if next Planned Visit Start Date is within the min/max window • If no record of PMV with planned visit start date AND no Closeout Visit record is planned or completed, include a record with the Planned Visit Start Date blank • If multiple PMVs have Planned Visit Start Dates, only the record with the earliest planned date will be included. • Unblinded visits are excluded from all calculations. 	Protocol Site Status Region Site Number Visit Date Range (Last Visit Actual Visit Completion Date) Monitor
Conversation Log	<p>Site information and details of communications between DCRI and site personnel. Includes communication type, date, description, keywords, name of person who created the record and the site contact name.</p> <p>This report should be viewed as a PDF document and should not be exported to Excel.</p>	Protocol Site Status Region Type Keyword Date Range Site
Conversation Log - Unblinded	<p>Site information and details of only unblinded communications between DCRI and site personnel. Includes communication type, date, description, keywords, name of person who created the record and the site contact name.</p>	Protocol Region Site Number
CRF - Unblinded	<p>A Listing of Unblinded Protocol by protocol, region, site number, trip report start date</p>	Protocol Region Site number Trip report Start date
DCRI Shipping Site List	<p>Contact information for Study Coordinators presented in a predefined format required by the DCRI Shipping Group for shipment of materials to sites. (Fields that are over the character limit for the predefined format are highlighted in yellow.)</p>	Protocol Site Status

Report Name	Synopsis	Prompts
Demographics	Site information plus contact information (address, phone, fax and email) for active site personnel (site contact role does not have an end date).	Protocol Site Status Role Region Site
Document Expiry	<p>Listing of documents that have expired or will expire depending on the date range selected.</p> <p>Document Name pick list is based on the standard document list.</p> <p>Rules for inclusion on this report:</p> <ul style="list-style-type: none"> • Include only those documents that have an expiration date tracked. • If multiple documents with the same name and same description have been tracked, include only the one with the latest expiration date. • If both IRB Approval Letter and IRB Renewal Letter have been tracked, if the IRB Renewal Letter has a later expiration date than the IRB Approval Letter, only the IRB Renewal Letter will be included. • For documents that are tracked for Site Contacts - If multiple documents with the same name and same description, and the same Site Contact's name, include only the one with the latest expiration date. • If the Site Contact's role end date is PRIOR to the expiration date for the document, EXCLUDE from the report. • If the Site Contact's role end date is AFTER the expiration date for the document, INCLUDE on the report. <p>Documents that have already expired, based on the date range selected, are highlighted in red.</p>	Protocol Site Status Region Site Document Date Range

Report Name	Synopsis	Prompts
Document Tracking	<p>Document name, description, version date, status, status date and expiration date. For documents relating to site personnel, includes person's name and site role.</p> <p>The report output includes all statuses that have been tracked per document, indicating with an "X" the Current Document Status. The report can be run using a Prompt for Current Document Status. If Yes is selected at this prompt, the report output will include only the status marked as Current for each document.</p> <p>The report also includes any documents in the Activity Plan that have not yet had a status tracked (shows what items are missing).</p> <p>The document name pick list is populated from documents included on the protocol specific Activity Plan. DO NOT use this filter if all documents are desired in results, regardless of whether they are included in the Activity Plan.</p>	Protocol Site Status Region Site Document Current Document Status
DRAFT Trip Report	<p>This report allows users to review trip reports before they are approved AND also includes Internal Comments. A PDF of the trip report is created with the watermark "DRAFT."</p>	Protocol Site Visit Name

Report Name	Synopsis	Prompts
DUHS eIRB Submission Report	<p>Includes only Sites with a current Site Status of Active. Default output is to an Excel document and includes: Protocol Name, Site Number, Site Status, Account Name, City, State and Country for the Account, Role of Principal Investigator, PI First Name, PI Last Name, PI Phone, and Email, IRB Name, IRB Approval Expiration Date, FWA # and FWA Expiration Date.</p> <p>The columns listed below are populated from the Site Management Screen tab/View tabs:</p> <ul style="list-style-type: none"> • IRB Name - Acct Affiliation View tab. • IRB Approval Expiration Date - Documents View tab for the Document of IRB Approval Letter OR the IRB Renewal Letter if its expiration date is later than the expiration date for the IRB Approval Letter. If multiple document records are tracked with the same Document Name and Document Description, the record with the latest expiration date will appear on the report. • The FWA # - Documents View tab, Comments Field for the Document of FWA # (may be blank if study is not federally-funded). • FWA # Expiration – Documents View tab, FWA # Document Expiration Date. If multiple records are tracked, the report will populate with the latest expiration date (may be blank if study is not federally-funded). 	

Report Name	Synopsis	Prompts
IRB Renewal Summary - Detail	<p>Detailed listing of all sites included in the counts on the IRB Renewal Summary report that is distributed to ADs on a monthly basis. Report includes expiry columns and expiration dates.</p> <p>Rules for Inclusion on this Report:</p> <ul style="list-style-type: none"> • Sites with the status of “Stop” or “Closed” will not be included. • Only the IRB Approval Letter or IRB Renewal Letter documents will be included. • If multiple documents with the same name have been tracked, only the one with the EARLIEST date of IRB Approval and LATEST date of IRB Renewal will be included. • If the IRB Renewal Letter is tracked and has an expiration date later than the IRB Approval Letter expiration date, only the IRB Renewal Letter will be included. • Documents will be matched by name only. Description will not be taken into consideration. 	Protocol
Milestones List	All Milestones, including Description, Planned Date and Completed Date. Includes any Milestones in the Activity Plan that have not had a Planned or Completed date tracked (shows what items are missing).	Protocol Site Status Milestone Region Site
Monitoring Visit Documentation Metrics	<p>A listing of Site Visit information including metrics between Visit Complete and Follow-Up Letter Sent, Visit Complete to Expense Report Submitted, Visit Complete to Expense Report Approved and Expense Report Submitted to Expense Report Approved.</p> <p>Results include only Site Visit records that have an Actual Visit Completion date populated. Metrics are calculated in Days. Calculations are done only if both dates are populated.</p>	Protocol Visit Type Region Site Trip Report Submitted by Trip Report Approved by Expense Report Submitted by Expense Report Approved by

Report Name	Synopsis	Prompts
Monthly CRA Productivity	<p>Summary data displayed by Protocol, month(s), and CRAs. Includes for each CRA by month, the total number of Visits planned, total number of Visits completed, totals for travel time, time on site, and planning/reporting time. Also includes by CRA, the total visit time (sum of travel time, time on site and planning/reporting time), and averages for travel time, time on site and planning/reporting time. Overall totals and averages for Protocol are also included.</p> <p>The average calculations are based on only those visits where the time field has been completed. (For example: Average Travel Time equals the total of Travel Time, divided by the number of visits where the travel time does not equal zero.)</p>	Protocol Month(s)
Protocol Detail	<p>Site demographics, Principal Investigator and Study Coordinator contact information, critical milestones (earliest date) and last conversation log (latest date).</p> <p>Report includes only PI and SC who are active (site contact role does not have an end date).</p> <p>IRB Approval is pulled from the Approval Letter Document.</p> <p>This report should be viewed as a PDF document and should not be exported to Excel.</p>	Protocol Site Status Region Site
Protocol Deviation	<p>A listing of Protocol Deviations by site, to include PD Type, Sub-type (Site or Subject), Subject initials and Subject number, if applicable, PD date, PD description, PD action description, and discovered Site Visit date.</p>	Protocol Site Status Date Range Region Site
Protocol Deviation- Unblinded	<p>For protocols with unblinded functionality, a listing of unblinded Protocol Deviations by site, to include PD Type, Sub-type (Site or Subject), Subject initials and Subject number, if applicable, PD date, PD description, PD action description, and discovered Site Visit date.</p> <p>Access will be limited to users who have unblinded access to individual protocols.</p>	Protocol Site Status Date Range Region Site

Report Name	Synopsis	Prompts
Regulatory Status	<p>A listing by site of items (Documents and Milestones) typically required for a site to be considered Regulatory Complete. Items included are:</p> <p>Received from Site and Approved by DCRI statuses for Documents: FDA 1572, PI CV, PI Financial Disclosure, ICF, and IRB Approval Letter (earliest date for each).</p> <p>Received from Site status for Documents: Confidentiality Agreement, Protocol Signature Page and IRB Roster (earliest date for each).</p> <p>Completed date for Milestones: IRB Submission, Regulatory Complete, and Activated for Enrollment (earliest) date.</p> <p>This report also includes First Patient Enrolled Date.</p>	Protocol Site Status Region Site
Safety Letter	<p>A listing by site of Trial Safety Letter data, including: Description, Case Number, Sequence and Version Date.</p> <p>If tracked, will also include dates for Sent to Site, Submitted to IRB, IRB Acknowledgement Received, Submission Letter Received and Sent to Sponsor.</p>	Protocol Site Status Date Range Region Site
Site Issue Log	<p>A listing, by Site, of Issues tracked on the Site Issue Log. The report output defaults in Excel and includes:</p> <p>Protocol Name, Region, Site #, PI Name, City and State, Issue Type, Description, Date Identified, Date Due, Status, Date Completed, Resolution/Action Comments, Assigned To and Created By.</p>	Protocol Region Site # Type Status Assigned To Date Ranges for Date Identified, Date Due and Date Completed
Site Personnel Essential Document & Training Exceptions	<p>A listing of MISSING documents and training that are expected for the site contact roles of Principal Investigator and Sub-Investigator.</p> <p>The Documents are limited to: CV, Medical License, Financial Disclosure, BioSketch and Conflict of Interest.</p> <p>The Training is limited to: Human Research Training.</p> <p>The report results will display the Protocol Name, Region, Site Status, Site Number, PI Last Name, PI First Name, Document/Training Name, Site Contact Role, Last Name and First Name, based on the selections at reach prompt, and for those site contacts who DO NOT have these items tracked.</p>	Protocol Site Status Site Role (limited to the ones listed) Document/Training (limited to the ones listed)

Report Name	Synopsis	Prompts
Site Progress and Enrollment Metrics	<p>A listing by site of items (Documents and Milestones) typically required for a site to be Activated for Enrollment. Items included are:</p> <p>Completed Date (earliest date) for Milestones of: Contract Sent, Contract Executed, Interest Pack Sent, Reg Pack Sent, Regulatory Complete, IP Sent, Starter Box Sent, and Activated for Enrollment.</p> <p>This report also includes: First Subject Enrolled, Last Subject Enrolled, and Total Number of Subjects (based on criteria used to run the report), plus enrollment metrics calculated for Days from Activated to First Subject Enrolled, Days since IP Sent, and Days since Last Subject Enrolled.</p> <p>The SM First Name and SM Last Name columns are populated from the name added in those fields on the main Site Form.</p>	Protocol Region Site Number
Site Status and Milestones	<p>A listing, by site, of current Site Status plus Completed Date for Milestones. Will include Milestones in the Activity Plan plus any added ad hoc (shows items that are missing).</p> <p><i>(Due to limitations of the reporting application, the date format in this report is yyyyymmdd000000 without dashes or slashes to separate the numbers).</i></p>	Protocol Site Status Region Site
Site Status History	<p>A listing, by site, of Site Statuses reached. Includes the date for each status, the Sub-status, if applicable, and associated comments.</p>	Protocol Region Site
Site Visit Detail	<p>A listing, by Site, of data tracked for Site Visits and Trip Reports. Includes Planned and Actual dates for Site Visits, plus the status of each Visit; status and dates for Trip Report Submitted, Trip Report Approved and Trip Report Sent to Sponsor; name of Monitor who submitted the report and name of the Trip Report Approver.</p> <p>This report includes both Planned and Completed site visit records.</p>	Protocol Visit Type Region Monitor Site
Site Visit Follow-Up	<p>A listing, by Site, of Follow-Up items tracked at the Site Visit level. Includes the visit date, follow-up item type and description of follow-up item. If a follow-up item has been closed, the report will include the resolution comment and the closed date.</p>	Protocol Region Monitor Site

Report Name	Synopsis	Prompts
Site Visit Metrics	<p>A listing, by Site, of the last completed monitoring visit date (for any Visit Type), days since the last visit (based on date report is run), enrollment before last completed visit, enrollment since last visit completed visit, current enrollment and next planned visit date.</p> <p>These Site Visit metrics are often used for future site visit scheduling.</p>	Protocol Region Site
Site Visit Productivity by Monitor	<p>By Protocol and Monitor, a listing of site visits that are planned or completed, including hours spent on site visits and trip report completion. Monitor name is that of the person who submitted the trip report.</p> <p>At the summary level, averages are calculated for travel time, time on site and planning/reporting time. The summary level also includes the total number of visits completed and the total number of visits planned but not completed.</p> <p>The average calculations are based on only those visits where the time field has been completed. (For example: Average Travel Time equals the total of Travel Time, divided by the number of visits where the travel time does not equal zero.)</p>	Protocol Monitor Visit Type Date
SSU - Contract Iterations	A listing of all Contract types, Date Sent, Date Received and Date Fully Executed, plus all contract statuses, status dates, SSU Team Member name and Comments from the main site form.	Protocol Site Status Region Site
SSU - ICF Iterations	<p>A listing of ICF documents and all statuses that have been tracked for each document. Includes IRB type, Central or Local, identification of Current document status, and document status comment field.</p> <p>ICF document will be included on this report regardless of whether a document status has been tracked</p>	Protocol Site Status Region Site

Report Name	Synopsis	Prompts
SSU – Site Activation	<p>A listing by Site of predetermined Milestones typically used by the Site Start-up Group to assess a Site’s progress to Site Activation.</p> <p>Items included are:</p> <p>PLANNED dates for Milestones of IRB Submission and IRB Meeting for sites using a LOCAL IRB.</p> <p>COMPLETED dates for Milestones of Reg Pack Sent, Contract Sent, Reg Pack Received, IRB Submission, IRB Meeting, IRB Approval, Regulatory Complete, Contract Executed, Site Hand Off and Activated for Enrollment for all sites.</p> <p>Contract Received Date, Current Contract Status and Current Contract Status Date.</p> <p>Comments from the main site form, SSU Team Member, CRA and Site Manager Names</p> <p>If a Milestone has not been tracked, the date field will be blank.</p> <p>The Central or Local IRB column is populated from data entered on the Account Affiliations Tab (first) or the Other Requirements Tab for the question: “Is Site using Central IRB”.</p> <p>The SIV Date is populated from the Site Visit Tab, for the Visit Type of either Site Selection/Initiation OR Site Initiation, with the earliest Actual Visit Completion Date.</p>	<p>Protocol Site Status Region Site</p>
SSU - Site Contracts Conversation Log	<p>Details of communications tracked on the Conversation Log view tab, using keyword of “Contract.”</p>	<p>Protocol Date Range Site</p>
SSU - Site Identification	<p>A listing of the Document Feasibility Questionnaire and the Contract Type Confidentiality Agreement. Included are all statuses and status dates tracked for these two items and identification of the current status. Report includes designation of Local or Central IRB. The column “Document Status Comments” is populated from the Comments field on the main site form, only for the Feasibility Questionnaire document.</p>	<p>Protocol Site Status Region Site</p>
Training	<p>A listing of Training Events tracked for site personnel. Includes the Training Type, Training Description, Site Personnel Name and Role, and the Training Event Status, Status Date and Expiration Date.</p> <p>Results include completed training events as well as those that have not been completed (shows what is missing).</p>	<p>Protocol Site</p>

Report Name	Synopsis	Prompts
Trip Report Completion Metrics - Detail	<p>A listing of Site Visit and Trip Report information. Shows metrics for Visit Complete to Trip Report Submitted, Visit Complete to Trip Report Approved, Visit Complete to Sent to Sponsor, Initial Trip Report Submitted to Trip Report Approved, Trip Report Approved to Sent to Sponsor and Visit Complete to Follow-up Letter Sent.</p> <p>Results include only Trip Reports that have been Approved.</p> <p><i>*Date Range Filter is based on the Trip Report Approval date. (example: if a Visit was completed in November, but the Trip Report was not Approved until December then the Trip Report will not appear in month of November date range)</i></p>	Protocol Site Status Training Role Region Site

Report Name	Synopsis	Prompts
<p>Trip Report Metrics by Monitor</p>	<p>Information presented in this report includes, by Protocol, monitors' progression of Trip Report completion.</p> <p>At the summary level, the following averages are calculated for each monitor:</p> <ul style="list-style-type: none"> • Number of days from Visit Complete to the first Trip Report Submitted Date • Number of internal review cycles until Trip Report Approval • Number of days from Visit Complete Date to Trip Report Approved Date <p>The summary level also includes the following percentages for each monitor:</p> <ul style="list-style-type: none"> • Trip Reports at an Approved status • Trip Reports Submitted on time • Trip Reports Approved on time <p>This report is based on the following rules:</p> <ul style="list-style-type: none"> • Visits must have an Actual Visit Completion Date in CTMS • The prompt of "Monitor" is populated using the name of any monitor who has ever submitted a Trip Report within the selected protocols • Monitor Name is determined from the Submitted By field of the completed visit • The "Trip Report Approved" field uses the EARLIEST date if a trip report was approved multiple times • The following fields are based on the Sponsor's contractual requirements. If this data has not been provided to CTMS Support for entry into CTMS, then no data will be displayed in these fields: 1st Draft Due, 1st Draft Submitted on Time, and TR Approved on Time. • Business days are used for calculations • The "Current Days Since Visit" field is not populated for Trip Reports that are Approved or Sent to Sponsor. • The "Number of days to Trip Report Approved" is the number of business days calculated from the Visit Complete Date to the Trip Report Approved Date. If the Trip Report Approved Date is not available, today's date will be used, cell will be colored red, & excluded from the average. If both the Visit Complete Date and the Trip Report Approved Date are not available the cell will be empty with no color. 	<p>Protocol Date Range* Region Site</p>

Report Name	Synopsis	Prompts
<p>Trip Report Metrics by Protocol</p>	<p>Information presented in this report includes summary Trip Report completion data by Protocol and Visit Type.</p> <p>At the summary level, the following totals are calculated for each protocol:</p> <ul style="list-style-type: none"> • Visits to Date • Trip Reports Submitted • Trip Reports Approved • Trip Reports Sent to Sponsor • Reports Submitted on time • Reports Approved on time <p>The summary level also includes the following percentages for each protocol:</p> <ul style="list-style-type: none"> • Trip Reports Submitted • Trip Reports Approved • Trip Reports Sent to Sponsor • Reports Submitted on time • Reports Approved on time <p>This report is based on the following rules:</p> <ul style="list-style-type: none"> • The "Trip Report Approved" field uses the EARLIEST date if a trip report was approved multiple times 	<p>Protocol Monitor Site status Site Visit type Visit complete (date range)</p>

Report Name	Synopsis	Prompts
Trip Report Metrics by Site	<p>Information presented in this report includes, by Protocol, monitors' progression of Trip Report completion.</p> <p>At the summary level, the following averages are calculated for each monitor:</p> <ul style="list-style-type: none"> • Number of days from Visit Complete to the first Trip Report Submitted Date • Number of internal review cycles until Trip Report Approval • Number of days from Visit Complete to Trip Report Approved Date <p>The summary level also includes the following percentages for each monitor:</p> <ul style="list-style-type: none"> • Trip Reports at an Approved status • Trip Reports Submitted on time • Trip Reports Approved on time <p>This report is based on the following rules:</p> <ul style="list-style-type: none"> • Visits must have an Actual Visit Completion Date in CTMS • Monitor Name is determined from the Submitted By field of the completed visit • The "Trip Report Approved" field uses the EARLIEST date if a trip report was approved multiple times • The following fields are based on the Sponsor's contractual requirements. If this data has not been provided to CTMS Support for entry into CTMS, then no data will be displayed in these fields: 1st Draft Due, 1st Draft Submitted on Time, and TR Approved on Time. • Business days are used for calculations • The "Current Days Since Visit" field is not populated for Trip Reports that are Approved or Sent to Sponsor. • The "Number of days to Trip Report Approved" is the number of business days calculated from the Visit Complete Date to the Trip Report Approved Date. If the Trip Report Approved Date is not available, today's date will be used, cell will be colored red, & excluded from the average. If both the Visit Complete Date and the Trip Report Approved Date are not available the cell will be empty with no color. 	Protocol Visit type Visit complete (date range)
		Protocol Site Site status Visit type Monitor Visit complete (date range)

