THERADEX ONCOLOGY
RAVE REFERENCE SHEET - VERSION 1.0
For CTMS Sites

Version	Date	Updated by	Approved by	Date Approved
1.0	April 25, 2018	Cynthia Neydon, CRA II	Diane Kuth	25 Apr 2018

OVERVIEW

Theradex Oncology is pleased to provide this reference sheet to CTMS sites for use when completing Electronic Case Report Forms (eCRFs) in iMedidata Rave. The document is intended to be a supplement to the CTMS Rave Users Guide; it includes eCRFs where queries are commonly generated and provides information to help with data entry. This document does not serve as an all-encompassing manual and instead is intended to provide additional guidance to individuals conducting data entry for NCI/ETCTN studies.

Objective

- Provide additional guidance to CTMS sites and new staff members
- Decrease the number of queries generated among study sites
- Produce consistent data for Lead Principal Investigators

Data Entry Expectations

- Read the official CTMS Rave Users Guide for complete instructions
- Refer to the Rave Reference Sheet for additional information
- Use the Study Calendar in the protocol as a data entry guideline; all tests required on the study calendar must be entered in Rave (e.g., ECG, labs, physical exams)
- When multiple reporting options are available, one consistent reporting method should be used throughout the study (e.g., unit of measure for tumor lesions)
- Per CTEP guidelines, submit patient data within two weeks of the patient completing a course of study treatment; respond to data queries within two weeks of their posting
- Contact the Theradex Oncology Data Management group or your site's Clinical Research Associate with questions

CASE REPORT FORM INSTRUCTIONS

General Data Entry Guidelines

- Partial dates in log format eCRF
  - Un/OCT/2010
  - Un/UNK/2010
  - Leave the field blank if the month, day, and year are unknown
- Times
  - All times should be recorded on a 24-hour clock
  - Midnight is entered as 00:00
  - Leave the field blank if the time is unknown

Case Report Form	Instructions
ENROLLMENT	**Informed Consent Version** – it is preferred that the version date listed on the Informed Consent Form (ICF) signed by the patient be reported; the internal tracking number can be used only if it is listed on the copy of the ICF signed by the patient
HISTOLOGY AND DISEASE	**Date of Diagnosis** – enter the original diagnosis date based on the pathology report or method of diagnosis appropriate for the disease state (if biopsy/surgery not an option); the date of the biopsy/procedure should be entered, not the date it was read **Date of Confirmation of Histology** – if the original diagnosis was many years prior to study enrollment and/or the patient was diagnosed with metastatic disease, the date of the most recent confirmation of histology PRIOR to study entry that re-confirms the original diagnosis and/or metastatic disease should be entered; the date of the biopsy/procedure should be entered, not the date it was read; the date can be the same as the date of diagnosis, if that is the only confirmation of histology
LESION EVALUATIONS	**Organ** – from the drop down list, chose the organ associated with the lesion being evaluated; the organ for a lymph node is "lymph node" **How Measured** – enter how the lesion was measured (e.g., CT, MRI); the same method should be used throughout the study for a specific lesion **Measurements** - for protocols using RECIST, lymph nodes = Measure X is the short axis; for non-nodal lesions = Measurement X is the long axis; for non-measurable lesions, the measurement fields should be left blank and

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	the **Evaluation Code** should be used to assess the lesion at each time point **Evaluation #** - 0 (zero) is the baseline evaluation and subsequent evaluations are numbered sequentially; the evaluation number corresponds to the date of the evaluation, so if a new lesion is found, it will have the same evaluation number (e.g., 1, 2, 3) as the other measurements obtained on that date; for crossover studies, when crossing over to the new treatment, sequential numbering is continued from study start and not restarted at crossover; the first evaluation prior to starting the crossover treatment will have the Time Period listed as "baseline" **Units of measure** - the same unit of measure must be used for each lesion and at every evaluation (mm/cm); consult the protocol for the correct measurement unit to use
BASELINE MEDICAL HISTORY	A brief description of major medical and surgical events during the patient's lifetime should be entered; physical exam findings should not be entered, the condition (or diagnosis) causing the symptom/finding should be entered; disease-related surgeries and procedures done for the on-study diagnosis should be entered on the Prior Surgery Supplement eCRF, not on the Baseline Medical History eCRF
PRIOR TREATMENT SUMMARY	The information on the Prior Treatment Summary eCRF (e.g., date of last dose) must match with the information entered on the Prior Therapy Supplement, Prior Surgery Supplement, and Prior Radiation Supplement eCRFs
PRIOR THERAPY SUPPLEMENT	Enter the patient's disease-related prior therapies for the on-study diagnosis
PRIOR SURGERY SUPPLEMENT	Enter the patient's disease-related prior surgeries, biopsies and procedures for the on-study diagnosis; procedures done during the patient's life time that are not related to disease should be reported on the Baseline Medical History eCRF
PRIOR RADIATION SUPPLEMENT	Enter the patient's disease-related prior radiation treatments for the on-study diagnosis
ADVERSE BASELINE SYMPTOMS	The purpose here is to provide a clinical picture of the patient on Course 1, Day 1 (C1D1), or at screening, prior to taking the first dose of study drug; this snapshot will aid in determining if future events should be entered on an Adverse Event (AE) eCRF (if the event does not worsen after baseline, it

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	usually does not need to be entered on an AE eCRF) List the adverse baseline symptoms the patient is experiencing, including lab abnormalities and symptoms; all symptoms must have a CTCAE term and a grade listed; symptoms not present on C1D1 should not be entered on this form; if the start date is unknown, leave the start date field blank Conditions the patient has a history of, but are not currently active on C1D1, should be entered on the Baseline Medical History eCRF; source documentation of adverse baseline symptoms, including onset date, grade, and relationship to disease, should be in the patient's medical record
CONCOMITANT MEASURES/MEDICATIONS	Enter all concomitant measures and medications taken during the study (e.g., IV fluid, thoracentesis, paracentesis, antiemetics, antidiarrheals, non-protocol related radiation); concomitant measures and medications for AEs should be listed All columns/fields, except stop date (if administration is ongoing), should be completed on the form for each medication/measure entered (note: the default for the Item field is "1" - it should never be removed and only be incremented if there is the need to enter the same drug on a new line for the same start date – for example, if the dose was given STAT and then PRN, one line should be Item 1 and the other Item 2)
TRANSFUSION	PRBC and platelet infusions the patient receives during the study should be entered
COURSE INITIATION	On day 1 of the patient's course complete this form; all other forms for this course are dependent on this form (e.g., addition of Adverse Event eCRF to the folder) **Start Date of Course** - the date the patient takes the first dose of study drug for that particular course **Arm and Treatment Assignment Code** (TAC) – using the drop down list, select the Arm and TAC the patient was registered to; this information usually stays the same at every course TAC changes can only be made as specified in the protocol (e.g. 1, the patient experiences a dose limiting toxicity (DLT) during Course 1 and the protocol allows a change in the TAC; e.g. 2, the protocol has a crossover to a new treatment upon disease progression); dose holds and reductions due to toxicities do not change the TAC recorded on the Course Initiation eCRF **Weight, Height, BSA** - refer to the study calendar and enter this

Case Report Form	Instructions
	information if required per protocol **CTEP Treating Institution Code** – Record the unique CTEP institution code as listed on the enrollment confirmation sheet; do not use dashes or spaces when entering the code
DRUG ADMINISTRATION	Information from the medication diary, pharmacy drug accountability record form (DARF) and clinic notes should be used to complete the Drug Administration eCRF; discrepancies between the subject medication diary, pharmacy DARF, and clinic notes should be entered on the course-specific Comments eCRF **Planned Dose** - the dose the physician prescribes for the specific course; if the prescribed dose changes mid-course, a new log line should be started and the new planned dose entered **Planned Schedule** - how often the patient takes the medication (e.g., daily) **Actual Total Dose** - the total amount of study drug taken for the date(s) listed on the log line; Planned Dose x Duration = Actual Total Dose When Planned Dose x Duration ≠ Actual Total Dose due to non-compliance (e.g. the patient accidently took 100 mg daily instead of the planned dose of 200 mg daily), enter a comment on the Comments eCRF to explain the discrepancy **Duration** - the duration (e.g., days, minutes) the study drug was taken/given; one log line can be entered for continuous dosing, if the planned dose and frequency do not change during the course; if doses are NOT given DAILY then each dose must be reported on a separate log line; new log lines should be entered for dose holds and dose reductions; a comment should be entered on the Comments eCRF to explain dose holds and dose reductions
ADVERSE EVENTS	AEs present during a course should be entered on the AE eCRF; events that started during a course but did not resolve during that course should be entered on all subsequent course AE eCRFs until resolution; the resolved date of the AE should be reported in the course during which it resolved (it is not necessary to enter it in the prior courses) Lab related AEs should have corresponding labs for the respective dates on the lab eCRFs; for hypertension/hypotension, corresponding vitals should be provided on the Vital Signs eCRF AEs that occur during the final observation period (typically 30 days after last dose of study drug) should be reported on the AE eCRF for the last

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	course AEs with a grade of 3 or higher should have a corresponding source document to indicate if the Principal Investigator considers it a serious AE (e.g., important medical event); all serious AEs require expedited reporting via CTEP-AERS **Attribution** - for protocols that have both commercial and investigational agents, attributions should be captured in accordance to that of the investigational agent **Action** - list the action taken with study drug; if the study drug was held, discontinued, or dose reduced due to the AE, the appropriate action should be entered (e.g., regimen interrupted, therapy discontinued, interrupted & reduced). **Therapy** - indicate if treatment was given for the AE; if treatment was given, it should be listed on the Concomitant Measures/Medication eCRF. Definitions of therapy types - **Symptomatic** for any concomitant medication used to treat an AE (e.g., antibiotics, ibuprofen, antiemetics, antidiarrheals); **Supportive** for concomitant medications and measures used to support the patient during the event (e.g., oxygen, IV fluids, heating pads); **Vigorously Supportive** for life saving measures (e.g., CPR, ventilator, blood products, vasopressors, surgery) **Outcome** - the outcome should be "still under observation/treatment" at all courses until resolution; when the event resolves enter the appropriate final status (i.e., recovered, alive with sequelae, or died) on the Course AE eCRF that corresponds to the date the event resolved
COURSE ASSESSMENT	**Start Date of Course** - the date the patient takes the first dose of study drug for the course; this date is populated automatically from the start date reported on the Course Initiation eCRF (note: a few very old studies require manual input) **Response Assessment** – if a response assessment was done during the course, enter the patient's best disease state - e.g., Stable Disease (SD), Partial Response (PR); if a response assessment was not required per protocol during the course, enter "not applicable per protocol;" if a response assessment was required per protocol, but was not done, enter "Not Assessed" and provide the reason it was not done per protocol in the Response Note field; if PD is due to clinical progression (no affiliated radiological examination performed), a comment indicating this should be entered in the Response Note field [Note: if the patient has a PR reported during the study, this will usually be

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	carried forward on every course assessment form unless the patient has Progressive Disease (PD); CDUS does not allow declining responses other than PD, unless otherwise defined in the protocol] **Date of Response** - enter either the date of the earliest evaluation which, upon confirmation, justifies an assessment of Complete Response (CR), PR, Marginal Response (MR), or SD, **or** enter the date the assessment was done during the given course (whichever data entry method is selected should be continued throughout the study); if an assessment was not done during the course, the field should be left blank; if the patient had PD during the course, the field should be left blank **Date of Progression** - if the patient had radiologic PD, enter the date of the evaluation (e.g., scan) that showed PD; the field should be left blank otherwise; [note: for clinical progression, leave this field blank and enter a comment regarding clinical progression in the Response Note field] **Course Disposition** - if the patient completed the course, enter "completed;" enter "discontinued" if the decision to permanently remove the patient from the study was decided before the end of the course **Dose Change from TAC** - if there was any deviation in the TAC listed on the Course Initiation eCRF (e.g., a missed dose, shortened course, longer course, dose reduction), the answer to this question will be either "yes, planned" or "yes, unplanned;" it is a planned change if the decision was made on the first day of a course prior to taking study drug (e.g., dose reduction from a previous course); it is an unplanned change if the decision was made after the first day of the course (e.g., missed dose or dose reduction due to an AE that started mid-cycle)
LITERAL LABS	Select the applicable procedure/test from the drop down list; provide the body site, indicate if normal or abnormal, and enter results; Screening procedures/tests (e.g., ECGs) and diagnostic procedures/tests occurring during the study (e.g., due to an adverse event) should be entered. Diagnostic procedures/tests not on the drop down list should be entered on the **Unanticipated Labs eCRF** Therapeutic procedures (e.g., paracentesis) done during the study should be entered on the **Concomitant Measures/Medication eCRF**
OFF STUDY	**Date off Treatment** - the date the physician made the decision to no longer treat the patient with study drug; it could be a later date than the date the patient took the last dose of study drug **Off Study Date** - the date the patient is off study and all follow-up has been completed per protocol

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	Reason - the reason the patient was taken off treatment should be listed; if the patient completed the treatment portion per protocol, but discontinued during the follow-up period, that reason should be listed; Note: if PD is due to clinical progression (no affiliated radiological examination performed), this should be reported as Off-Study Other Reasons – Clinical Progression (within the Explain field) **Best Response** - record the best overall response to treatment while on Protocol (CR, PR, SD, MR, or PD) **Date of Best Response** - enter the date the best response (CR, SD, PR, MR) was first observed during the study; the date must be consistent with the date recorded on the Course Assessment eCRF(s) and with evaluations on the Lesion Evaluations eCRF; if the patient did not have a positive response, leave the field blank **Date of Progression** - if the patient had documented PD (radiologic, pathologic, or other method) during the study, enter the date here; the date must be consistent with the date recorded on the Course Assessment eCRF(s) and with evaluations on related eCRF(s) (e.g., Lesion Evaluations eCRF, Bone Marrow eCRF); if the patient did not have documented PD, leave the field blank [note: patients who are taken off study for clinical progression should not have a date of progression reported; the Date of Progression field should be blank.]
FOLLOW UP	Follow-up forms should be completed if required per protocol; enter the date of contact and patient status; add a new log line to record subsequent contacts
LATE ADVERSE EVENTS	Enter AEs that occur during the follow-up period and cannot be associated with the last course of treatment (i.e., AEs occurring after the patient has completed the normal observation period per protocol, which is typically 30 days after the last dose of study drug)