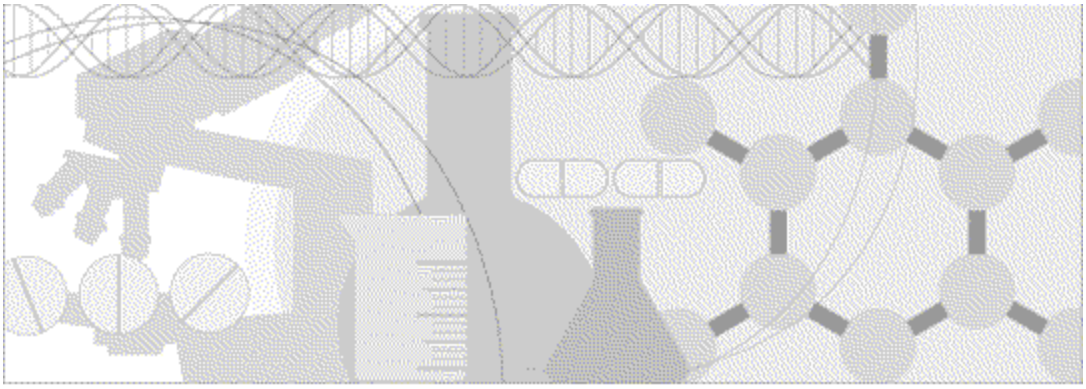
Oracle Health Sciences ClearTrial Cloud Service 5.5.1

Working with Expert Algorithms



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Overview

For resources or costs that are not part of the ClearTrial default model, you can create an algorithm to generate the level of effort hours (for resources) or monetary value (for costs). You can use the following to create your algorithms:

- Multiple expressions
- Scripted algorithms

Best practice is to use the multiple expression functionality to define your algorithms whenever possible. However, if you are unable to produce the correct level of effort in hours or monetary cost value using multiple expression algorithms, ClearTrial offers Plan Enterprise license users the Expert Algorithm Editor role. The expert algorithm functionality provides greater flexibility by giving users the ability to create custom mathematical formulas via a scripting language. The scripting language used to define the formulas is a subset of JavaScript.

JavaScript

JavaScript is a programming language used in web applications to make the applications do what you want them to do. Most websites you access through the internet run off of JavaScript.

Since the usage of expert algorithms in ClearTrial is limited to producing a numeric value (either hours or cost value), only a limited subset of JavaScript functionality is available to be used in ClearTrial to express algorithms.
There are various websites available on the internet to learn more about JavaScript. There are specific rules you should understand to use JavaScript. For example, JavaScript **is case sensitive**. Although you do not need to be a software developer or expert in JavaScript, review of some of the websites is recommended.

A good website to learn more about JavaScript is http://www.w3schools.com/js/default.asp.

Available JavaScript Functionality

The JavaScript-based formulas in ClearTrial can use the following:

- Arithmetic operations available:
  - Addition (+)
  - Subtraction (-)

    - Multiplication (*)
    - Division (/)

- JavaScript comparison operators available:
    - >, >=, <, <=, == (two equal signs), !=, === (three equal signs)

- JavaScript logical operators available:
    - &&
    - ||

- JavaScript Math functions available (all are case sensitive):
    - Use Math.round(x) to return the value of x rounded to its nearest integer; *Math.round(1.6) returns 2*
    - Use Math.floor(x) to return the value of x rounded downward to its nearest integer; *Math.floor(1.6) returns 1*
    - Use Math.ceil(x) to return the value of x rounded up to its nearest integer; *Math.ceil(1.2) returns 2*
    - Use Math.max() to find the highest value in a list of arguments; *Math.max(5, 10, 15) returns 15*
    - Use Math.min() to find the lowest value in a list of arguments; *Math.min(5, 10, 15) returns 5*
    - The following are less common Math functions that are valid to use in ClearTrial:
        - Use Math.abs(x) to return the absolute (positive) value of x; *Math.abs(-4.7) returns 4.7*
        - Use Math.sqrt(x) to return the square root of x; *Math.sqrt(144) returns 12*
        - Use Math.pow(x,y) to return the value of x to the power of y; *Math.pow(8,2) returns 64*
        - Use Math.exp to return e (Euler's number) raised to the power of the value provided as parameter; *Math.exp(1) returns 2.718*
        - Use Math.log to return the logarithm of the given parameter; *Math.log(10) returns 2.303*

- JavaScript keywords available:
    - if, else, true, false, switch, case, break, default

- JavaScript characters available:

- upper or lowercase letters of the alphabet, numbers, dot, comma, arithmetic operators (as listed above), underscore, ?, :, ;, =, <, >, !, $, &, |, (,), {, }

- Conditional statements available (all are case sensitive):
  - if / else if / else
    - Use "if" to specify code to be executed if the specified condition is true.
    - Use "else" to specify code to be executed if the specified condition is false.
    - Use "else if" to specify a new condition to test, if the first condition is false.

```
if (condition) {
  code to be executed if the condition is true
} else {
  code to be executed if the condition is false
}
```

```
if (condition1) {
  code to be executed if condition1 is true
} else if (condition2) {
  code to be executed if condition1 is false and condition2 is true
} else {
  code to be executed if condition1 and condition2 are both false
}
```

- Switch / case
  - Use "switch" to specify many alternative blocks of code to be executed
    - The switch expression is evaluated once.
    - The value of the expression is compared with the values of each case.
    - If there is a match, the associated block of code is executed.

```
switch(expression) {
   case x:
     code to be executed if case x is matched
      break;
   case y:
     code to be executed if case y is matched
      break;
   default:
      code to be executed if previous cases are not matched
}
```

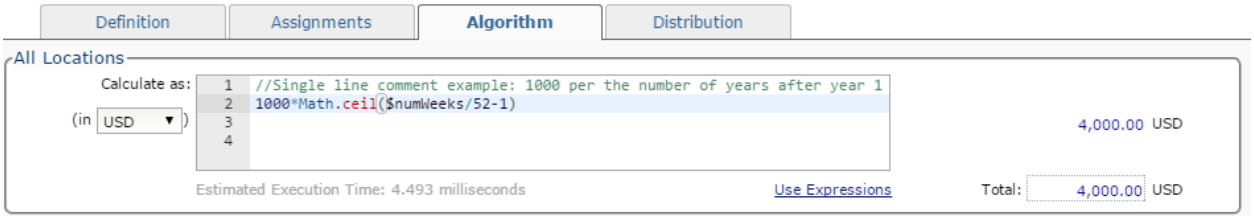
Using Comments

ClearTrial allows you to input comments along with algorithm formulas to explain what the formula is trying to accomplish and to make it more readable to other users.

Single line comments start with //.

Any text between // and the end of the line will be ignored by JavaScript (will not be executed as it is not considered part of the formula).

Example:



Multi-line comments start with /* and end with */.

Any text between /* and */ will be ignored by JavaScript.

Example:

You can review the website http://www.w3schools.com/js/js_comments.asp for more information on adding comments with JavaScript.

Autoformatting and Autocompletion

ClearTrial automatically formats your task/resource algorithm script to make it easier to read and understand.

- For each row of a script for task/resource algorithms, a unique line number displays as the first character for the row.
- The first line number will always be "1," and each subsequent line number will follow sequential numbering logic.
- ClearTrial will indent a new line/row automatically when the user presses Enter after a leading bracket.

Variable name and keyword suggestions are provided with related descriptions, so that you can quickly find and select items from a pre-populated list to ensure you use valid variable names or keywords in the script.

- You can click a selection from the pre-populated list and the selection will be inserted into the script.
- When a pre-populated list is displayed, a description displays next to each list item.
- As you type your script, ClearTrial identifies any syntax that is invalid and highlights what has caused the error.
- Because brackets often are troublesome, when you place the cursor near a bracket, the matching pair of the bracket is highlighted.

Validation as You Type

ClearTrial helps you write scripts in valid JavaScript syntax by providing information about the script's validity as you create it. This prevents you from saving scripts that will not execute properly. Validation checks include:

- Scripts must be valid JavaScript whose last statement evaluates to the value desired.

- Scripts must only use the following JavaScript keywords: if, else, true, false, switch, case, break, default.
- Scripts must not contain double or single quotes or any characters other than: upper or lowercase letters of the alphabet, numbers, dot, comma, mathematical operators (+,-,*,/,%), underscore, ?, :, ;, =, <, >, !, $, &, |, (,), {, } , space, or newline.
- Scripts must not contain variables that are not defined/exposed with respect to the plan in which the scripts are created.

Estimated Execution Time

If the script is valid, ClearTrial provides an estimate of execution time, so you can adjust the run-time characteristics of your script.

If the estimated execution time is large, it may end up impacting the overall performance of the plan. You are then recommended to review the algorithm to see if there is a more efficient way it can be formulated.

Variables

Expert algorithms can use any valid variable to help calculate hours or costs.

A variable represents a ClearTrial work unit/cost driver or a custom field. For example, ***$numLocations*** is the name of the ClearTrial variable which represents the number of locations in a plan. You can reference the ***$numLocations*** variable in a scripted algorithm instead of inputting the actual number of locations (if a plan has 3 locations, you can use ***$numLocations*** in the scripted algorithm instead of inputting a value of 3). If a user adds or removes locations on the Location tab, the value that ***$numLocations*** represents will automatically update to reflect the current number of locations in the plan.

Items that are considered properties of a task or cost are not considered assumptions by ClearTrial and are not available as variables to be referenced in expert algorithms (e.g. assigned provider, billing rate location, GL code, and department).

There are over 200 ClearTrial system variables that exist that can be used in a plan's script formula. The ClearTrial system variables that can be used in a plan will depend upon the plan's assigned cost model. See ***Appendix A*** for a listing of

ClearTrial system variables. ClearTrial system variables will always start with $ (dollar sign).

Custom fields can also be used in a plan's script formula. You can reference a custom field in a script formula by using the name given to the custom field when it was created. Custom field variables will not start with $ (dollar sign).

The custom fields that can be used in a plan will depend upon the plan's assigned custom field model.

Tips and Recommendations

- Use expert algorithms only if you are unable to construct your algorithm using multiiple expressions.
- JavaScript is case sensitive. If your algorithms are producing errors, double check the syntax and variable names used to ensure the right upper and/or lowercase letters are being used.
- If your expert algorithm divides by a variable, it is recommended to add a conditional statement to return 0 if the variable value equates to 0. This will ensure that if the variable value is 0, your formula will evaluate to 0 instead of generating an error.

  Consider the following formula: (1000 / $numNewsletters);

  If $numNewsletters = 0, then the above formula is dividing by 0 which will cause the algorithm to generate an error.

  To avoid the possibility of dividing by 0, use a conditional statement:

  ```
  if (0 == $numNewsletters) {0;}
  else {1000 / $numNewsletters;}
  ```

  You can also use a JavaScript ternary operator: (1000 / ($numNewsletters > 0 ? $ numNewsletters : 1));

  - In English, the denominator says if $numNewsletters is greater than 0, then use that value in the formula, else use 1 for the value of $numNewsletters.
  - NOTE: using the ternary operator in this example will make the formula produce a value > 0 even if the value of the variable is

0. If you do not want the formula to produce a value > 0 when the variable is 0, then use the if…else statement.

- When attempting to compare values, always use == (double equal sign) instead of = (single equal sign). The = (single equal sign) means something slightly different in JavaScript.
  - Example:
    - Right syntax: 4 == $numLocations
    - Wrong syntax: 4 = $numLocations
- To round a value to a certain number of decimals, use the Math.pow function.
  - Examples:
    - To round up 1.678 to 1.68, use *Math.ceil(1.678 * Math.pow(10, 2)) / Math.pow(10, 2)*
    - To round down 1.678 to 1.67, use *Math.floor(1.678 * Math.pow(10, 2)) / Math.pow(10, 2)*

- When using the "and" and "or" operators, be sure to use 2 pipes for "or" and two ampersands for "and." Using a single pipe or single ampersand will perform a bitwise comparison and, although legal syntax, will not produce the desired result.

  - Example:

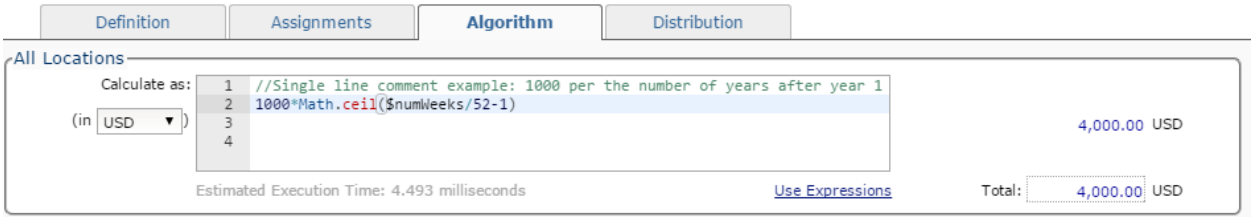
```
Right:    if( $isEdc || $isEdcThirdParty )
Wrong:  if( $isEdc | $isEdcThirdParty )

Right:    if( $isEdc && $edcMaturityLevel == 4 )
Wrong:  if( $isEdc & $edcMaturityLevel == 4 )
```

Expert Algorithm Examples

Example: Using commentary

For long or complex algorithms, it is recommended that you use comments to explain what the algorithm is attempting to do. This helps other users understand the algorithm logic without having to translate the actual algorithm line by line.

Here is an example of a single line comment using the "//" syntax.



Anything after "//" on a single line will be ignored by the application.

Here is an example of multi-line comments using the "/*" and "*/" syntax.

Type "/*" to start the commentary and then end with "*/" after the commentary to tell the application to ignore anything typed in between.

You can review the website http://www.w3schools.com/js/js_comments.asp for more information on adding comments with JavaScript.

Example: Using Math.ceil

This example will demonstrate how to use one of JavaScript's Math functions.

You want to a new custom cost to be calculated as the cost for annual fees as $1000 for each year of the plan after year 1.

1. On the Algorithm tab for the indirect cost, click Switch to Script to switch into script mode.

2. Using the ClearTrial variable, which exists for the number of weeks between study start date and final report (e.g., study duration), ***$numWeeks***, the user can then specify in the script box the cost algorithm script to be:

```
1000 * (Math.ceil($numWeeks / 52) – 1)
```

The Math.ceil function will round up the output to the nearest integer.

This is equivalent to the following Excel formula, assuming the number of weeks is located in cell A1: (1000 * (roundup(A1 / 52, 0) – 1))

You can review the website http://www.w3schools.com/js/js_math.asp for more information on JavaScript Math functions.

Example: Conditional formula using if…else

You want to create a scripted algorithm to drive the level of effort in hours for a custom resource based on the EDC maturity level selected for the plan. If the EDC maturity level selected is 1, then the level of effort should be 2 hours; if the level selected is 2, then the level of effort should be 1.5 hours; for any other selected level, the level of effort should be 0.5 hours.

1. On the Algorithm tab for the task/resource, click Switch to Script to switch into script mode.
2. Using the ClearTrial variable that exists for the EDC maturity level, ***$edcMaturityLevel***, the user can then specify in the script box the conditional task/resource algorithm script to be:

```
if (1 == $edcMaturityLevel) {2;}      <<if edc maturity level is 1, then 2 hrs;
                                        the semi-colon at the end tells
                                        JavaScript to stop if the condition is
                                        true
else if (2 == $edcMaturityLevel) {1.5;} <<if edc maturity level is 2, then 1.5
                                            hrs
else {.5;}   <<for any other maturity level, then .5 hrs
```

You can review the website http://www.w3schools.com/js/js_if_else.asp for more information on using JavaScript if/else statements.

Example: Conditional formula using if…else with multiple conditions

You can also have multiple conditions you may want the application to evaluate in your if/else formulas.

Let's say that in addition to $edcMaturityLevel, you also want to put a condition on the number of subjects based on the following:

- If the EDC maturity level selected is 1 AND the number of subjects is < 40, then the level of effort should be 2 hours;
- If the level selected is 1 AND the number of subjects is >= 40, then the level of effort should be 2.5 hours.

Using the "&&" operator, you can specify in the script box the multi-conditional algorithm script to be:

```
if (1 == $edcMaturityLevel && 40 > $numSubjects) {2;}
else if (1 == $edcMaturityLevel && 40 <= $numSubjects) {2.5;}
else if (2 == $edcMaturityLevel) {1.5;}
else {.5;}
```

If you want to base your condition on an OR statement, you can use the operator "||".

Let's say you want 1.5 hours if $edcMaturityLevel is a 1 or a 2. Using the "||" operator, you can specify in the script box the multi-conditional algorithm script to be:

```
if (1 == $edcMaturityLevel || 2 == $edcMaturityLevel) {1.5;}
else {.5;}
```

Be careful to use the logical AND and OR operators and not their bitwise counterparts. Always use 2 pipes and two ampersands to combine values.

Example: Conditional formula switch/case

Using the same scenario from the previous example, we can also create a formula using the switch/case statement.

1. On the Algorithm tab for the task/resource, click Switch to Script to switch into script mode.

2. Using the ClearTrial variable which exists for the EDC maturity level, ***$edcMaturityLevel***, the user can then specify in the script box the conditional task/resource algorithm script to be:

```
switch ($edcMaturityLevel) {   <<specify which variable is being evaluated
    case 1: 2          <<if edc maturity level is 1, then 2 hrs
        break;         <<"break" tells JavaScript to stop if case 1 is true
    case 2: 1.5        <<if edc maturity level is 2, then 1.5 hrs
            break;
    default: .5        <<for any other value, then .5 hrs
    }
```

You can review the website http://www.w3schools.com/js/js_switch.asp for more information on using JavaScript switch statement.

Truthiness

When using a variable that evaluates to a Boolean (yes or no) value, you can skip the comparison to a specific value, because JavaScript will treat any positive non-zero value as "true."

For example, you can write:

```
if( $isEdc )
```

instead of

```
if ( $isEdc == 1 )
```

Both will evaluate to either true or false based on whether the Data Collection Method is "Electronic Data Capture."

Conversely, you can write:

```
if( !$isEdc )
```

instead of

```
if( $isEdc != 1 )     or      if( $isEdc === 0 )
```

APPENDIX A: Listing of all valid ClearTrial variables

CLEARTRIAL VARIABLE	DESCRIPTION
$bioFactor	Indication-specific factor of complexity
$edcFactor	Indication-specific factor of complexity related to EDC
$edcMaturityLevel	Represents the choice of maturity level for EDC
$indicationID	Numeric identifier of the Indication
$isCrossoverTrialDesign	Will subjects cross between treatment arms (e.g. Latin Square) (value of 0 = NO, 1 = YES)
$isEDC	Indicates whether data collection method is Electronic Data Capture (value of 0 = NO, 1 = YES)
$isEDCThirdParty	Indicates whether Electronic Data Capture is done by a third-party (value of 0 = NO, 1 = YES)
$isElectronicDiary	Indicates whether subject diary pages are online (value of 0 = NO, 1 = YES)
$isEndpointTrial	Indicates whether the trial is modeled as an endpoint trial (value of 0 = NO, 1 = YES)
$isMedicalMonitoring24by7	Indicates whether 24 x 7 medical monitoring is expected (value of 0 = NO, 1 = YES)
$isOnsiteMonitoringUsed	Indicates whether onsite monitoring visits are expected (value of 0 = NO, 1 = YES)
$isParallelTrialDesign	Will treatment arms run in parallel with separate subject populations (value of 0 = NO, 1 = YES)
$isPhaseFourNoInd	Is this a Phase IV (No IND) trial (value of 0 = NO, 1 = YES)
$isPhaseFourWithInd	Is this a Phase IV (With IND) trial (value of 0 = NO, 1 = YES)
$isPhaseOneHV	Is this a Phase One (Healthy Volunteers) trial (value of 0 = NO, 1 = YES)
$isPhaseOneOncologyOrVaccines	Is this a Phase One Oncology or Vaccines trial

CLEARTRIAL VARIABLE	DESCRIPTION
	(value of 0 = NO, 1 = YES)
$isPhaseThree	Is this a Phase III trial (value of 0 = NO, 1 = YES)
$isPhaseTwo	Is this a Phase II trial (value of 0 = NO, 1 = YES)
$isPhoneBasedMonitoringUsed	Indicates whether onsite monitoring visits are expected (value of 0 = NO, 1 = YES)
$medicalMonitoringFactor	Indication-specific factor of complexity related to medical monitoring
$mohDelay	Location-specific regulatory delay
$monitoringTimeRequiredForBaselineVisit	The number of minutes required to monitor pages collected during baseline visit
$numBednightsDuringWashoutPeriod	The number of bednights expected during washout period
$numBedNightsTreatmentA	The number of nights subjects will be confined to the study center for treatment A
$numBedNightsTreatmentB	The number of nights subjects will be confined to the study center for treatment B
$numBedNightsTreatmentC	The number of nights subjects will be confined to the study center for treatment C
$numBedNightsTreatmentD	The number of nights subjects will be confined to the study center for treatment D
$numBedNightsTreatmentE	The number of nights subjects will be confined to the study center for treatment E
$numCohortEscalationReviews	The number of cohort escalation reviews
$numCohortEscalationReviewsTreatmentA	The number of cohort escalation reviews for treatment A
$numCohortEscalationReviewsTreatmentB	The number of cohort escalation reviews for treatment B
$numCohortEscalationReviewsTreatmentC	The number of cohort escalation reviews for treatment C
$numCohortEscalationReviewsTreatmentD	The number of cohort escalation reviews for treatment D

CLEARTRIAL VARIABLE	DESCRIPTION
$numCohortEscalationReviewsTreatmentE	The number of cohort escalation reviews for treatment E
$numCrfBooksPrinted	The number of CRF books to be printed
$numCrfPagesAudited	The number of CRF Page equivalents to be audited
$numCrfPagesInBaselineVisit	The number of CRF pages to be collected during baseline visit
$numCrfPagesPerExtendedVisitTreatmentA	The number of CRF pages per extended visit for treatment A
$numCrfPagesPerExtendedVisitTreatmentB	The number of CRF pages per extended visit for treatment B
$numCrfPagesPerExtendedVisitTreatmentC	The number of CRF pages per extended visit for treatment C
$numCrfPagesPerExtendedVisitTreatmentD	The number of CRF pages per extended visit for treatment D
$numCrfPagesPerExtendedVisitTreatmentE	The number of CRF pages per extended visit for treatment E
$numCrfPagesPerScreenFailure	The number of CRF pages collected for each screen failure
$numCrfPagesPerSubjectTreatmentA	The number of CRF pages per subject for treatment A
$numCrfPagesPerSubjectTreatmentB	The number of CRF pages per subject for treatment B
$numCrfPagesPerSubjectTreatmentC	The number of CRF pages per subject for treatment C
$numCrfPagesPerSubjectTreatmentD	The number of CRF pages per subject for treatment D
$numCrfPagesPerSubjectTreatmentE	The number of CRF pages per subject for treatment E
$numCrfPagesWithDrops	Total number of CRF pages expected, accounting for subject drop rate
$numCrfPagesWithoutDrops	Total number of CRF pages expected if no subjects drop
$numDataImports	The number of data imports expected
$numDataTransfers	The number of data transfers expected
$numDaysActiveTreatment	The number of days between FSI and LSO
$numDaysFromDbLockToDraftReport	The number of days from Database Lock to delivery of draft report
$numDaysFromDbLockToFinalReport	The number of days from Database Lock to delivery of final report

CLEARTRIAL VARIABLE	DESCRIPTION
$numDaysFromDbLockToStatReport	The number of days from Database Lock to delivery of stat report
$numDaysFromFirstSiteToLastSite	The number of days from FSA to LSA
$numDaysFromFsiToEndpoint	The number of days from FSI to Endpoint date
$numDaysFromFsiToFso	The number of days from FSI to FSO
$numDaysFromFsiToLsi	The number of days from FSI to LSI
$numDaysFromFsiToLso	The number of days from FSI to LSO (the active treatment period)
$numDaysFromFsoToLsi	The number of days from FSO to LSI
$numDaysFromFsoToLso	The number of days from FSO to LSO
$numDaysFromLsiToEndpoint	The number of days from LSI to Endpoint date
$numDaysFromLsiToLso	The number of days from LSI to LSO
$numDaysFromLsoToDbLock	The number of days from LSO/LSLV to Database Lock
$numDaysFromStartToFirstSite	The number of days from PASD to FSA
$numDaysFromStartToFsi	The number of days from PASD to FSI
$numDaysFromStartToGlobalFsi	The number of days from PASD to Global FSI
$numDaysFromStartToGlobalLsi	The number of days from PASD to Global LSI
$numDaysFromStartToLastSite	The number of days from PASD to LSA
$numDaysFromStartToLsi	The number of days from PASD to LSI
$numDaysFromStartToLso	The number of days from PASD to LSO/LSLV
$numDaysTreatmentA	The duration of treatment A (in days)
$numDaysTreatmentB	The duration of treatment B (in days)
$numDaysTreatmentC	The duration of treatment C (in days)
$numDaysTreatmentD	The duration of treatment D (in days)
$numDaysTreatmentE	The duration of treatment E (in days)
$numDiaryPagesPerExtendedVisitTreatmentA	The number of subject diary pages per extended visit for treatment A
$numDiaryPagesPerExtendedVisitTreatmentB	The number of subject diary pages per extended visit for treatment B
$numDiaryPagesPerExtendedVisitTreatmentC	The number of subject diary pages per extended visit for treatment C
$numDiaryPagesPerExtendedVisitTreatmentD	The number of subject diary pages per extended visit for treatment D
$numDiaryPagesPerExtendedVisitTreatmentE	The number of subject diary pages per extended visit for treatment E

CLEARTRIAL VARIABLE	DESCRIPTION
$numDiaryPagesPerSubjectTreatmentA	The number of subject diary pages per subject for treatment A
$numDiaryPagesPerSubjectTreatmentB	The number of subject diary pages per subject for treatment B
$numDiaryPagesPerSubjectTreatmentC	The number of subject diary pages per subject for treatment C
$numDiaryPagesPerSubjectTreatmentD	The number of subject diary pages per subject for treatment D
$numDiaryPagesPerSubjectTreatmentE	The number of subject diary pages per subject for treatment E
$numDrugAccountabilityVisitsPerSite	The number of additional drug-accountability visits per site
$numDrugShipments	The total number of drug or device shipments
$numDrugShipmentsPerSite	The number of drug or device shipments to each site
$numDsmbReports	The number of DSMB reports expected
$numEdcTrainingSessions	The number of EDC Training Sessions expected
$numExpeditedSAEs	The number of SAE reports expedited to regulatory agencies and ethics committees
$numFourAndOneHalfDayMonitoringTrips	The number of four and one half day monitoring visits expected
$numFourDayMonitoringTrips	The number of four day monitoring visits expected
$numGrantPayments	The total number of grant payments
$numGrantPaymentsPerSite	The number of grant payments per site
$numHalfDayMonitoringTrips	The number of half day monitoring visits expected
$numHoursAvgMonitoringTravel	The average number of hours a monitor will need to travel to sites
$numHoursMedicalMonitoringPerSAE	The number of hours a medical monitor will spend with each SAE
$numHoursPhoneBasedMonitoring	The number of hours of phone-based monitoring expected
$numInterimAnalyses	The number of interim analyses expected
$numInvestigatorMeetings	The number of investigator meetings planned
$numLabDiagnosticTestsPerSubjectTreatmentA	The number of diagnostic tests per subject for treatment A

CLEARTRIAL VARIABLE	DESCRIPTION
$numLabDiagnosticTestsPerSubjectTreatmentB	The number of diagnostic tests per subject for treatment B
$numLabDiagnosticTestsPerSubjectTreatmentC	The number of diagnostic tests per subject for treatment C
$numLabDiagnosticTestsPerSubjectTreatmentD	The number of diagnostic tests per subject for treatment D
$numLabDiagnosticTestsPerSubjectTreatmentE	The number of diagnostic tests per subject for treatment E
$numLocations	The number of locations
$numMedicalDataListingReviews	The number of medical data listing reviews expected
$numMinutesCrfDataCoordination	The number of minutes (per page) for data coordination
$numMinutesCrfDataEntry	The number of minutes (per page) for data entry
$numMinutesQueryReview	The number of minutes to re-review queries/CRF data from a previous visit
$numMonitoringDays	The number of monitoring days expected
$numMonitoringMinutesPerCrfPageTreatmentA	The number of minutes to monitor each page for treatment A
$numMonitoringMinutesPerCrfPageTreatmentB	The number of minutes to monitor each page for treatment B
$numMonitoringMinutesPerCrfPageTreatmentC	The number of minutes to monitor each page for treatment C
$numMonitoringMinutesPerCrfPageTreatmentD	The number of minutes to monitor each page for treatment D
$numMonitoringMinutesPerCrfPageTreatmentE	The number of minutes to monitor each page for treatment E
$numMonitoringVisits	The number of monitoring visits expected
$numNewsletters	The number of newsletters expected
$numOneAndOneHalfDayMonitoringTrips	The number of one and one half day monitoring visits expected
$numOneDayMonitoringTrips	The number of one day monitoring visits expected
$numPharmacoEconomicPagesPerExtendedVisitTreatmentA	The number of pharmacoeconomic pages/extended visit for treatment A
$numPharmacoEconomicPagesPerExtendedVisitTreatmentB	The number of pharmacoeconomic pages/extended visit for treatment B
$numPharmacoEconomicPagesPerExtendedVisitTreatmentC	The number of pharmacoeconomic pages/extended visit for treatment C

CLEARTRIAL VARIABLE	DESCRIPTION
$numPharmacoEconomicPagesPerExtendedVisitTreatmentD	The number of pharmacoeconomic pages/extended visit for treatment D
$numPharmacoEconomicPagesPerExtendedVisitTreatmentE	The number of pharmacoeconomic pages/extended visit for treatment E
$numPharmacoEconomicPagesPerSubjectTreatmentA	The number of pharmacoeconomic pages/subject for treatment A
$numPharmacoEconomicPagesPerSubjectTreatmentB	The number of pharmacoeconomic pages/subject for treatment B
$numPharmacoEconomicPagesPerSubjectTreatmentC	The number of pharmacoeconomic pages/subject for treatment C
$numPharmacoEconomicPagesPerSubjectTreatmentD	The number of pharmacoeconomic pages/subject for treatment D
$numPharmacoEconomicPagesPerSubjectTreatmentE	The number of pharmacoeconomic pages/subject for treatment E
$numPreStudySiteVisits	The number of pre-study site visits
$numProtocolAmendments	The number of protocol amendments expected
$numPublications	The number of manuscripts or publications expected
$numQolPagesPerExtendedVisitTreatmentA	The number of Quality of Life pages per extended visit for treatment A
$numQolPagesPerExtendedVisitTreatmentB	The number of Quality of Life pages per extended visit for treatment B
$numQolPagesPerExtendedVisitTreatmentC	The number of Quality of Life pages per extended visit for treatment C
$numQolPagesPerExtendedVisitTreatmentD	The number of Quality of Life pages per extended visit for treatment D
$numQolPagesPerExtendedVisitTreatmentE	The number of Quality of Life pages per extended visit for treatment E
$numQolPagesPerSubjectTreatmentA	The number of Quality of Life pages per subject for treatment A
$numQolPagesPerSubjectTreatmentB	The number of Quality of Life pages per subject for treatment B
$numQolPagesPerSubjectTreatmentC	The number of Quality of Life pages per subject for treatment C
$numQolPagesPerSubjectTreatmentD	The number of Quality of Life pages per subject for treatment D
$numQolPagesPerSubjectTreatmentE	The number of Quality of Life pages per subject for treatment E
$numQueries	Represents the number of queries monitors are expected to resolve

CLEARTRIAL VARIABLE	DESCRIPTION
$numRepeatDataFigures	The number of repeat/copy data figures/graphs expected
$numRepeatDataListings	The number of repeat/copy data listings expected
$numRepeatDataTables	The number of repeat/copy data tables expected
$numRepeatPkPdDataFigures	The number of repeat/copy data PK/PD figures/graphs (*Phase 1 HV only*)
$numRepeatPkPdDataListings	The number of repeat/copy PK/PD data listings (*Phase 1 HV only*)
$numRepeatPkPdDataTables	The number of repeat/copy PK/PD data tables (*Phase 1 HV only*)
$numSAEs	The number of Serious Adverse Events expected
$numScreenFailsPaid	The number of screen failures for which the sponsor will pay
$numScreensPerCrfBook	The number of screens to be designed for the CRF book
$numScreensPerCrfPage	The average number of screens per CRF page
$numSiteCloseoutVisits	The number of site closeout visits
$numSiteInitiationVisits	The number of site initiation visits
$numSites	The number of sites
$numSitesIdentifiedBySponsor	The number of sites to be identified by the Sponsor
$numSitesIdentifiedByVendor	The number of sites to be identified by the vendor
$numSitesRequiringAudit	The number of sites requiring a QA audit
$numSitesUsingCentralIRB	The number of sites using a Central IRB/EC
$numSitesUsingLocalIRB	The number of sites using a local IRB/EC
$numSitesUsingLocalMonitoring	The number of sites using local monitoring
$numSitesWithOnsiteCOV	The number of sites requiring onsite close-out visits
$numSitesWithOnsiteSIV	The number of sites requiring site initiation visits (in-person)
$numSitesWithOverhead	The number of sites requiring overhead
$numSitesWithPhoneCOV	The number of sites requiring only phone-based close-out

CLEARTRIAL VARIABLE	DESCRIPTION
$numSitesWithPhonePSSV	The number of sites requiring a phone-based prestudy site visit
$numSitesWithPhoneSIV	The number of sites requiring only phone-based site initiation
$numSubjects	The number of subjects to be randomized
$numSubjectsFailScreen	The number of potential subjects that will fail screening
$numSubjectsPerSitePerMonth	The expected enrollment rate (subjects per site per month)
$numSubjectsToScreen	The number of potential subjects to be screened
$numSubjectsTreatmentA	The number of subjects randomized to Treatment A
$numSubjectsTreatmentB	The number of subjects randomized to Treatment B
$numSubjectsTreatmentC	The number of subjects randomized to Treatment C
$numSubjectsTreatmentD	The number of subjects randomized to Treatment D
$numSubjectsTreatmentE	The number of subjects randomized to Treatment E
$numSubjectsWillComplete	The number of subjected expected to complete all visits
$numSubjectVisits	The number of visits for all subjects
$numThirdPartyDataVendors	The number of third party data vendors or sources expected
$numThreeAndOneHalfDayMonitoringTrips	The number of three and one half day monitoring visits expected
$numThreeDayMonitoringTrips	The number of three day monitoring visits expected
$numTranslations	The number of languages into which documents must be translated
$numTwoAndOneHalfDayMonitoringTrips	The number of two and one half day monitoring visits expected
$numTwoDayMonitoringTrips	The number of two day monitoring visits expected
$numUniqueDataFigures	The number of unique data figures/graphs expected
$numUniqueDataListings	The number of unique data listings expected

CLEARTRIAL VARIABLE	DESCRIPTION
$numUniqueDataTables	The number of unique data tables expected
$numUniquePages	The number of unique CRF pages to be designed
$numUniquePkPdDataFigures	The number of unique PK/PD data figures/graphs (*Phase 1 HV only*)
$numUniquePkPdDataListings	The number of unique PK/PD data listings (*Phase 1 HV only*)
$numUniquePkPdDataTables	The number of unique PK/PD data tables (*Phase 1 HV only*)
$numVisitsTreatmentA	The number of weeks (or days) in which a subject visit occurs for treatment A
$numVisitsTreatmentB	The number of weeks (or days) in which a subject visit occurs for treatment B
$numVisitsTreatmentC	The number of weeks (or days) in which a subject visit occurs for treatment C
$numVisitsTreatmentD	The number of weeks (or days) in which a subject visit occurs for treatment D
$numVisitsTreatmentE	The number of weeks (or days) in which a subject visit occurs for treatment E
$numWeeks	The number of weeks between the study start date and the date the final report is due
$numWeeksEnrollment	The number of weeks expected for subject enrollment
$numWeeksProjectManagement	The number of weeks of Project Management expected
$numWeeksTreatmentA	The duration of treatment A (in weeks)
$numWeeksTreatmentB	The duration of treatment B (in weeks)
$numWeeksTreatmentC	The duration of treatment C (in weeks)
$numWeeksTreatmentD	The duration of treatment D (in weeks)
$numWeeksTreatmentE	The duration of treatment E (in weeks)
$pctRegulatoryDocsCollected	The percent of regulatory documents to be collected (value will be converted to a decimal)
$pctSdv	The percent of source document verification expected (value will be converted to a decimal)
$pctSiteOverhead	The average percent overhead for sites requiring overhead (value will be converted to a decimal)

CLEARTRIAL VARIABLE	DESCRIPTION
$pctSitesWithOnsitePSSV	The percent of sites requiring an onsite prestudy site visit (value will be converted to a decimal)
$pctSubjectsFailScreen	The percent of potential subjects that will fail screening (value will be converted to a decimal)
$queryRate	The percent of pages expected to generate queries (value will be converted to a decimal)
$therapeuticAreaID	Numeric identifier of the Therapeutic Area
$transportFactor	Location-specific transportation factor
$washoutPeriodDuration	Length of washout period, in weeks for late stage trials and days for Phase I trials

APPENDIX B: Listing of all ClearTrial therapeutic areas and indications with the associated ID values

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
Blood and Blood Forming Organs	1	Anemias	8
		Blood Dyscrasias	21
		Coagulation Defects	31
Circulatory System	2	Aneurysms	219
		Angina	12
		Atherogenic Dyslipidemia	261
		Atherosclerosis	17
		Atrial Fibrillation (Post Surgical)	256
		Cardiac Dysrhythmias	26
		Cardiomyopathy	27
		Conduction Disorders	34
		Congestive Heart Failure	35
		Deep Vein Thrombosis (DVT)	49
		Hemorrhoids	70
		Hypertension	75
		Lipid Metabolism	82
		Lipid Metabolism - Diabetic Dyslipidemia	221
		Lipid Metabolism - Hypertigyceridemia	222
		Lipid Metabolism - Mixed Dyslipidemia	223
		Metabolic Disorders	91
		Migraine	92
		Myocardial Infarction	93
		Peripheral Vascular Disease	115
		Restonosis	127
		Rheumatic Heart Disease	129
		Thrombosis	206
CNS	3	Alzheimer's/Dementia	6
		Anesthetics	9
		Aneurysms	11

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Anti-NSAIDs	14
		Epilepsy/Seizures	56
		Headaches	68
		NSAIDs	98
		Pain Regimens	108
		Paralysis	112
		Parkinson's	114
		Schizophrenia	134
		Stroke	205
		Stroke Recovery	229
		Subarachnoid Hemorrhage (SAH)	133
Dermatology	4	Acne	1
		Male Pattern Baldness	212
		Psoriasis	122
Ear	5	Developmental Disorders	44
		Hearing Loss	69
		Infections	77
Endocrine	6	Acromegaly	232
		Diabetes Mellitus, Type 1	208
		Diabetes Mellitus, Type 2	45
		Diabetic Nephropathy	259
		Diabetic Retinopathy	260
		Growth Factor Disorders	67
		Hormonal Dysfunction	74
		Hypoglycemia	76
		Menopause	88
		Osteoporosis	102
		Thyroid Disorders	141
Eye	7	Cataracts	28
		Conjunctivitis	36
		Glaucoma	65
		Keratoconjunctivitis	80
		Retinopathy	128
Genitourinary System	8	Cachexia - Chronic Renal Failure	257
		Chronic Kidney Disease (CKD)	235
		Endometriosis	55

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Genital Inflammatory Diseases	64
		Glomerulonephritis	236
		Hormonal Deficiencies	73
		Kidney Stones	81
		Menopause	89
		Nephritis, Cystitis	94
		PMS	119
		Polycystic Kidney Disease	249
		Prostatitis	121
		Renal Failure (Chronic Renal Failure)	124
		UTI	147
GI	9	Cholecystitis	207
		Constipation	38
		Crohn's Disease	258
		Diarrhea	46
		Diverticulitis	47
		Duodenal Ulcers	48
		Dysentery	209
		Dyspepsia	50
		Esophageal Stricture	58
		Functional Disorders	59
		Gastric Ulcers	61
		Gastric-Esophageal Reflux	62
		Gastritis	63
		Hepatitis	71
		Irritable Bowel Syndrome	78
		Liver Disease, Cirrhosis	84
		Noninfectious Enteritis, Colitis	95
		NSAIDs	96
		Pancreatitis	111
		Pouchitis/ Ulcerative Colitis	265
		Ulcerative Colitis/Proctitis	146
ID	10	Anti-infective (Bacterial Infections)	13
		Fungal	60
		Hepatitis C	211
		Parasitic	113

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Pelvic Inflammatory Disease (PID)	231
		Viral	149
Immunology	11	AIDS	3
		Lupus	86
		Lupus Nephritis	262
		Myasthenia Gravis	214
		Rheumatoid Arthritis	130
Medical Devices	20	Breast Reconstruction (Supportive)	253
		Facial Aesthetics Injectables	252
		Implantable Uterine Devices (Contraception)	220
		Medical Devices (Other)	87
		Reconstructive Breast Surgery (Implants)	255
		Surgical Weight Management (Balloon or Gastric Banding)	254
Mental Disorders Behavior Modification	12	ADD	2
		Alzheimer's/Dementia	7
		Behavior Disorders	8
		Cerebrotendinous Xanthamatosis	234
		Chemical Dependence	29
		Depression, Anxiety	43
		Eating Disorders	51
		Mental Retardation	90
		Personality Disorders	116
		Sleep Disorders	138
		Sleep Disturbances	267
Musculoskeletal System	13	Arthritis	15
		Bursitis	25
		Chondrosarcoma	240
		Connective Tissue Diseases	37
		Fibromyalgia	210
		Multiple Sclerosis	135
		Muscular Dystrophies	213
		NSAIDs	97

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Osteoarthritis	264
		Osteomyelitis	101
		Osteoporosis	103
		Rhabdomyolysis	216
		Rheumatology	131
		SLE/Autoimmune Disease Lupus	137
Nutritional Metabolic Disorders	14	Eating Disorders	52
		Obesity	99
Oncology	15	Acute Myelogenous Leukemia (AML)	218
		Adenocarcinoma (NOS)	237
		Basal Cell Carcinoma	238
		Bladder/Kidney	20
		Brain Cancer	22
		Breast Cancer	23
		Cervical Cancer	239
		Chronic Lymphocytic Leukemia	241
		Chronic Myelogenous Leukemia (CML)	242
		Colorectal Cancer	33
		Glioblastoma (GMB)	243
		Hodgkin's Disease	200
		Large B cell Lymphoma	244
		Liver Cancer	83
		Lung Cancer	85
		Melanoma	263
		Metastatic Melanoma	245
		Multiple Myeloma	225
		Nasopharyngeal Carcinoma/Throat Cancer	246
		Neuroblastoma	247
		Non Hodgkin's Lymphoma (NHL)	201
		Non Small Cell Lung Cancer (NSCLC)	202
		Ovarian Cancer	248
		Pancreatic Cancer	110

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Prostate Cancer	215
		Renal Carcinoma	227
		Reproductive System	125
		Sarcoma	150
		Skin Cancer	136
		Small Cell Lung	203
		Solid Tumor	204
		Stomach and Esophageal Cancer	250
		Testicular Cancer	251
Oral Medicine	16	Jaw, TMJ	79
		Mouth/Salivary Glands	92
		Teeth/Dental	140
Other	17	Anesthetics	10
		Bioresponse Modifiers	19
		Cold Remedies	32
		Contrast Media Studies	39
		Critical Care	41
		Emergency Medicine	53
		Erectile Dysfunction	57
		Oral Contraceptives	100
		Other (Complex)	104
		Other (Routine)	105
		Other (Simple)	106
		Other (Very Complex)	107
		Pain Regimens	109
		Renal Transplant	266
		Total Parenteral Nutrition (TPN)	142
		Transplant	143
		Trichomonas	144
		Vaccines	148
Respiratory	18	Allergies	5
		Asthma	16
		Bronchiectasis	233
		Bronchitis	24
		COPD	40
		Cystic Fibrosis	42
		Emphysema	54
		Pharyngitis	117

THERAPEUTIC AREA	THERAPEUTIC AREA ID	INDICATION	INDICATION ID
		Pneumonia, Influenza	120
		Pulmonary Heart Disease	123
		Respiratory Infections	126
		Rhinitis	132
		Sleep Apnea	217
		Tuberculosis	145
Sexually Transmitted	19	AIDS	4
		Chlamydia	30
		Gonorrhea	66
		Herpes	72
		Pelvic Inflammatory Disease (PID)	118
		Syphilis	139
		Trichomoniasis	230
(Healthy Volunteers)	21	(Healthy Volunteers)	268