CERTARA

Quantify Depression Clinical Outcomes Database

Summary Information

The Quantify Major Depression Disorder (MDD) Clinical Outcomes Database documents clinical efficacy and safety information from randomized and controlled regulatory trials investigating monotherapy and adjunctive therapy pharmaceutical drugs for major depression disorder and treatment-resistant depression.

Table 1. Summary information

Parameter	Description
format	Excel or KEEP format
indications	Major depression, treatment-resistant depression
references	103
trials	108
trial.arms	310
patients	31,907
data.rows	5,444
compounds	agomelatine, amitriptyline, aripiprazole, brexpiprazole, bupropion, citalopram, desvenlafaxine, duloxetine, escitalopram, fluoxetine, imipramine, maprotiline, mirtazapine, nefazodone, nortriptyline, olanzapine, paroxetine, placebo, quetiapine, sertraline, trazodone, venlafaxine, vortioxetine
key.efficacy.endpoints	hama, hamd, hamd remission, hamd responders, madrs, madrs remission, madrs responders
key.safety.endpoints	dropout ae, dropout le, dropout total, fatigue, headache, insomnia, nausea, sexual dysfunction, somnolence, weight gain

Features and Benefits

Key Features

- **Comprehensive:** includes information for marketed drugs; data sources include journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separate source database and linked to unique clinical trial names
- **Flexibility:** the database design allows for quick updates as well as expansions to include additional indications/drugs/endpoints/trials

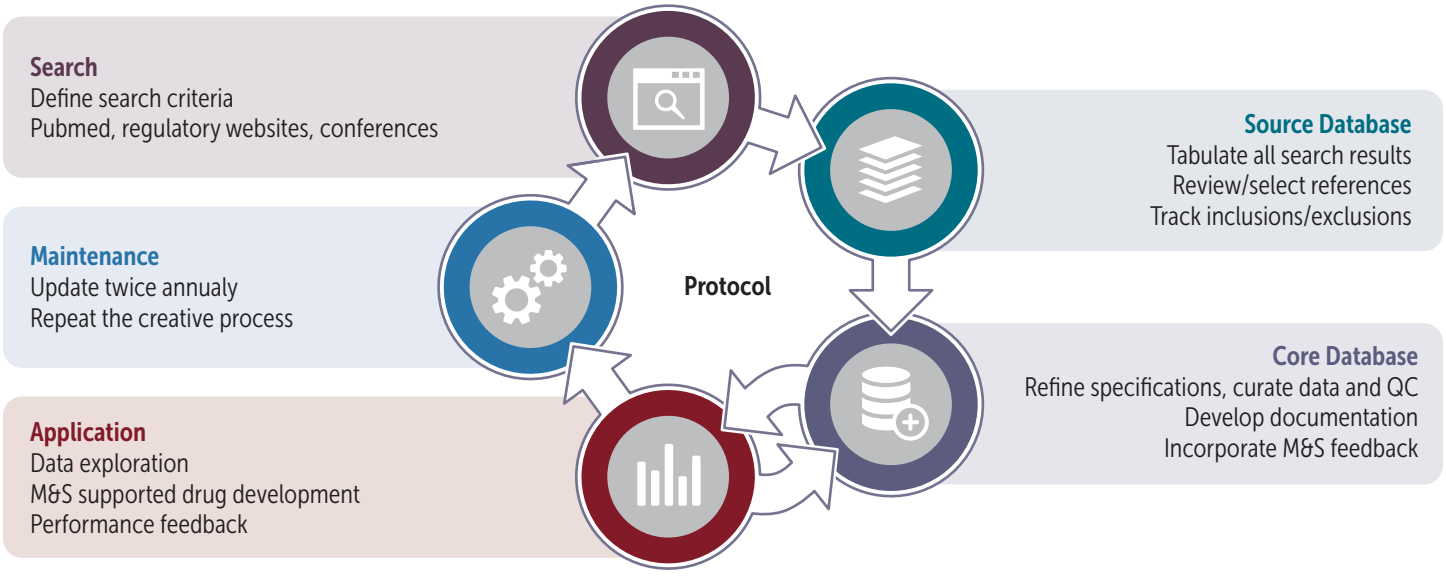
- **Model-friendliness:** designed and reviewed by experienced modelers to ensure highest quality and usability for modeling and simulation to support drug development strategies
- **Customizability:** can be augmented with clinical trial data proprietary to the client (this information goes into a separate proprietary database and will be owned by the client)

Why Use Our Databases

- Designed and managed by experienced modelers
- Provides most relevant data to support clients' needs for quantitative decision making
- Contains up-to-date and high quality data so that it is always readily available to provide timely analysis required to support critical clinical trial decisions
- Supported by additional services such as modeling and simulation consulting services and custom curation services (by our partner, GVK Bio)

Organization and Structure

This product consists of two databases, the Depression source database and the Depression clinical outcomes database. The source database is a database that maintains the sources of information in the literature. The clinical outcomes database contains the information on trial, treatment and patients characteristics and efficacy results of the trials identified for inclusion in the database.



Outcome Fields

The clinical outcomes database contains information from 108 trials, representing 310 unique treatment arms and about 31,907 patients. There are a total of 5,444 rows in the database. The table below provides an overview of the available data for randomized treatments, ie, treatments that were started at time of randomization and not present as background therapy. The table shows the number of treatment arms and the number of patients for each study drug.

Table 2. Number of trials, treatment arms and patients by drug

randomized.drug	trials	arms	patients
agomelatine	7	10	1103
amitriptyline	6	6	320
aripiprazole	2	2	374
brexpiprazole	4	7	1132
bupropion	1	2	241
citalopram	13	19	2350
desvenlafaxine	4	9	1238
duloxetine	9	12	1332
escitalopram	10	11	1608
fluoxetine	30	34	2769
fluoxetine+olanzapine	5	9	657
imipramine	15	15	876
maprotiline	1	1	35
mirtazapine	4	4	201
nefazodone	4	6	385
nortriptyline	1	1	68
olanzapine	5	5	413
paroxetine	17	19	1639
placebo	86	86	8992
quetiapine	6	11	1782
sertraline	2	4	427
trazodone	1	1	77
venlafaxine	19	25	2349
vortioxetine	5	11	1539
TOTAL	**108**	**310**	**31907**

The following endpoints are recorded in the database. The number of patients and time course of the endpoints were recorded.

Table 3. Category, number of trials, treatment arms and patients by endpoint

endpoint	category	trials	arms	patients
dropout ae	dropout	89	261	27758
dropout le	dropout	88	258	27144
dropout total	dropout	90	261	27260
fatigue	ae	22	66	9812
hama	hama	9	28	4425
hama-psychic anxiety	hama	4	12	1886
hama-somatic anxiety	hama	4	12	1886
hamd	hamd	91	251	24517
hamd-anxiety items	hamd	1	3	493
hamd-depressed mood	hamd	5	15	2332
hamd-sleep disturbance items	hamd	1	3	493
hamd-suicide	hamd	1	4	612
hamd remission	hamd	7	21	2683
hamd responders	hamd	10	31	3798
headache	ae	48	136	14892
insomnia	ae	43	129	15759
madrs	madrs	68	201	21971
madrs-apparent sadness	madrs	4	12	1839
madrs-concentration difficulties	madrs	4	12	1839
madrs-inability to feel	madrs	4	12	1839
madrs-inner tension	madrs	4	12	1839
madrs-lassitude	madrs	4	12	1839
madrs-pessimistic thoughts	madrs	4	12	1839
madrs-reduced appetite	madrs	4	12	1839
madrs-reduced sleep	madrs	4	12	1839
madrs-reported sadness	madrs	4	12	1839
madrs-suicidal thoughts	madrs	4	12	1839
madrs remission	madrs	15	45	7045
madrs responders	madrs	16	48	7519
nausea	ae	65	187	20453
psqi	sleep	5	15	2332
sexual dysfunction	ae	14	40	4819
somnolence	ae	45	131	14282
weight gain	ae	14	38	4592
TOTAL		**108**	**310**	**31907**

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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