CERTARA

Quantify AS Clinical Outcomes Database

Summary Information

The Quantify AS Clinical Outcomes Database is developed to document clinical safety and efficacy information from randomized controlled trials investigating biologics currently approved or in development for ankylosing spondylitis (AS).

Table 1. Summary information

Parameter	Description
format	Excel or KEEP format
indications	as, axspa
references	47
trials	36
trial.arms	81
patients	6,321
data.rows	3,118
compounds	adalimumab, apremilast, certolizumab, ct-p13, etanercept, golimumab, infliximab, pamidronate, placebo, sarilumab, secukinumab, sulfasalazine, tocilizumab
key.efficacy.endpoints	asas 5 of 6, asas pr, asas20, asas40, asas50, asas70, asdas, asqol, basdai, basdai50, basfi, basmi, chest expansion, crp, esr, inflammation, mases, modified schober's test, nocturnal pain, patient global assessment, physician global assessment, sf36 mental component summary, sf36 physical component summary, swollen joint count, tender joint count, total back pain

Features and Benefits

Key Features

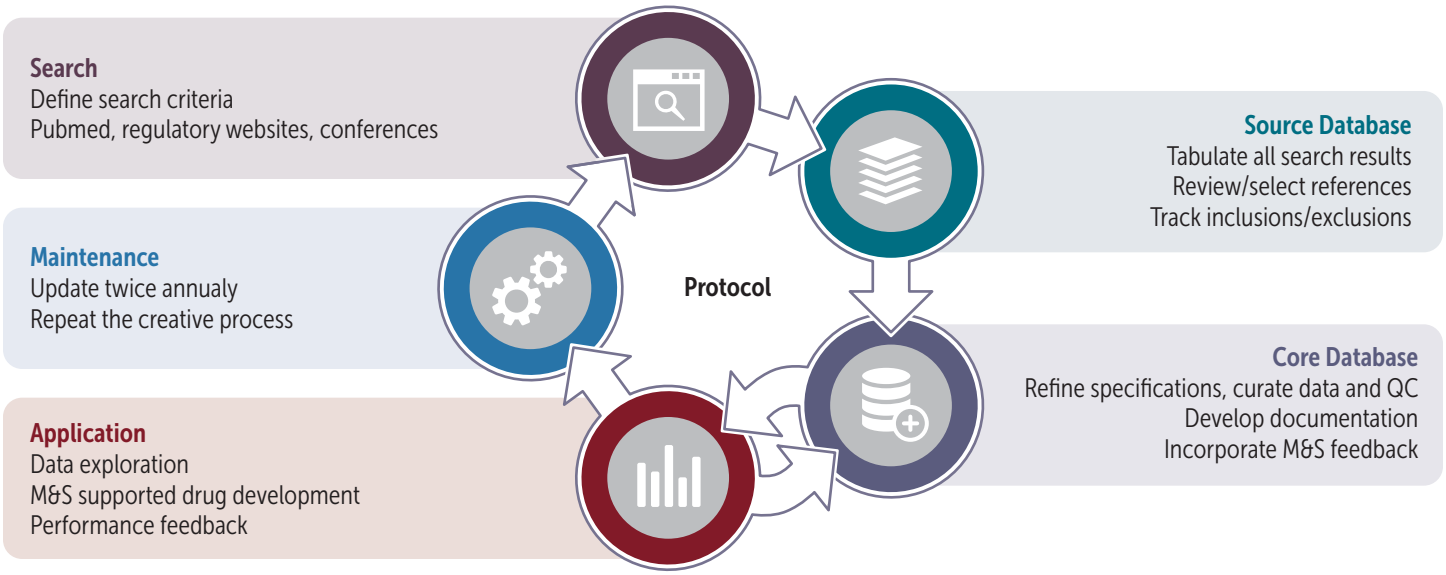
- **Comprehensive:** includes information for marketed drugs; data sources include journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separate source database and linked to unique clinical trial names
- **Flexibility:** 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 AS source database and the AS 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.



Overview of the AS Source Database

The primary data sources were controlled clinical trials published in the medical literature. 47 references were selected for inclusion in the clinical database. The detailed reference review (inclusion/exclusion) information is recorded in the source database. Additional data sources include FDA Summary Basis of Approval, clinicaltrials.gov, and immunology conference abstracts.

Outcome Fields

The clinical outcomes database contains information from 36 trials, representing 81 unique treatment arms and about 6,321 patients. There are a total of 3,118 rows in the database. The table below provides an overview of the available data for randomized treatments, i.e. 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
adalimumab	3	3	475
apremilast	1	1	163
certolizumab	1	2	218
ct-p13	1	1	125
etanercept	14	17	1334
golimumab	4	5	426
infliximab	7	7	559
pamidronate	1	1	10
placebo	29	29	1824
sarilumab	1	5	251
secukinumab	3	5	418
sulfasalazine	2	2	223
tocilizumab	3	3	295
TOTAL	**36**	**81**	**6321**

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

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

randomized.drug	trials	arms	patients
abdominal pain	11	28	2098
ae any	21	51	4956
ae serious	24	56	4644
alt increase	5	15	1399
anti-drug antibodies	3	6	612
anti-dsdna	1	2	40
antinuclear antibodies	2	4	82
arthralgia	4	9	520
arthritis	1	2	279
asas 5 of 6	16	40	3871
asas pr	19	46	4256
asas20	36	81	6321
asas40	24	57	4969
asas50	9	18	1048
asas70	8	16	1035
asdas	9	24	1750
asqol	5	11	566
ast increase	6	17	1481
asthenia	2	4	166
bas-g	5	10	907
basdai	30	68	5379
basdai20	4	9	672
basdai50	17	37	3016
basdai70	4	9	672
basdai90	1	2	213
basfi	26	55	4206
basmi	22	50	4139
bronchitis	3	6	270
cervical rotation	4	9	1032
chest expansion	11	27	2418
crp	21	47	3366
diarrhea	12	30	2290
dropout	10	22	2604
dropout ae	21	49	4393
dropout le	8	22	2274
drug discontinuation	1	2	279
early escape	6	12	1234
esr	10	20	975
fatigue	1	2	84
fatigue ae	5	15	1048
gastroenteritis	3	6	270
haq-5	1	2	344

infection	10	26	2959
infection rti	14	34	2864
infection serious	10	22	2634
infection uri	1	2	250
inflammation	10	26	2298
influenza	2	4	307
infusion reaction	4	8	641
injection site reaction	14	35	3106
intermalleolar distance	4	9	1032
lateral flexion	4	9	1032
mases	6	12	1158
mei	1	2	279
modified schober's test	8	17	1999
myalgia	1	2	30
nasopharyngitis	9	24	2144
nausea	9	20	2330
nocturnal and back pain	2	4	192
nocturnal pain	12	25	2401
pain ae	5	15	1102
patient global assessment	19	44	3670
patient global assessment of pain	1	2	344
pharyngitis	4	8	719
physician global assessment	13	26	1979
pruritis	5	10	517
pyrexia	2	4	280
rash	3	7	854
rhinitis	3	6	391
sf36 mental component summary	9	19	1818
sf36 physical component summary	10	22	2189
swollen joint count	12	24	2415
tender joint count	7	14	1806
total back pain	15	36	3443
tragus to wall	4	9	1032
wpai shp activity impairment	1	2	344
wpai shp overall work impairment	1	2	344
TOTAL	**36**	**81**	**133081**

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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