CERTARA

Quantify IPF Clinical Outcomes Database

Summary Information

The Quantify IPF Clinical Outcomes Database contains data from randomized clinical trials assessing pharmacological interventions for treatment of idiopathic pulmonary fibrosis.

Table 1. Summary information

Parameter	Description
format	Excel or KEEP format
indications	ipf, mild or moderate ipf, progressive ipf, well-defined ipf, early-stage ipf
references	40
trials	32
trial.arms	71
patients	7,405
data.rows	3,138
compounds	ambrisentan, azathioprine, bosentan, bromhexine hydrochloride, co-trimoxazole, colchicine, etanercept, everolimus, ifn gamma, imatinib, macitentan, n-acetylcysteine, nintedanib, no treatment, pirfenidone, placebo, prednisone, prm-151, sildenafil, warfarin
key efficacy endpoints	6mwd, acute exacerbation, disease progression, dlco, dlco predicted, dyspnea score, fvc, fvc predicted, pa-ao2, pao2, sgrq, spo2, tlc predicted
key safety endpoints	ae any, ae gi, ae serious, alt/ast elevation, anorexia, arthralgia, bronchitis, cough, death, death ipf, diarrhea, dizziness, dropout, dropout ae, dyspnea, fatigue, hr death, ipf worsening, nasopharyngitis, nausea, os, pneumonia, rash, respiratory failure, rti, rti lower, rti upper, vomiting, weight decrease

Features and Benefits

Key Features:

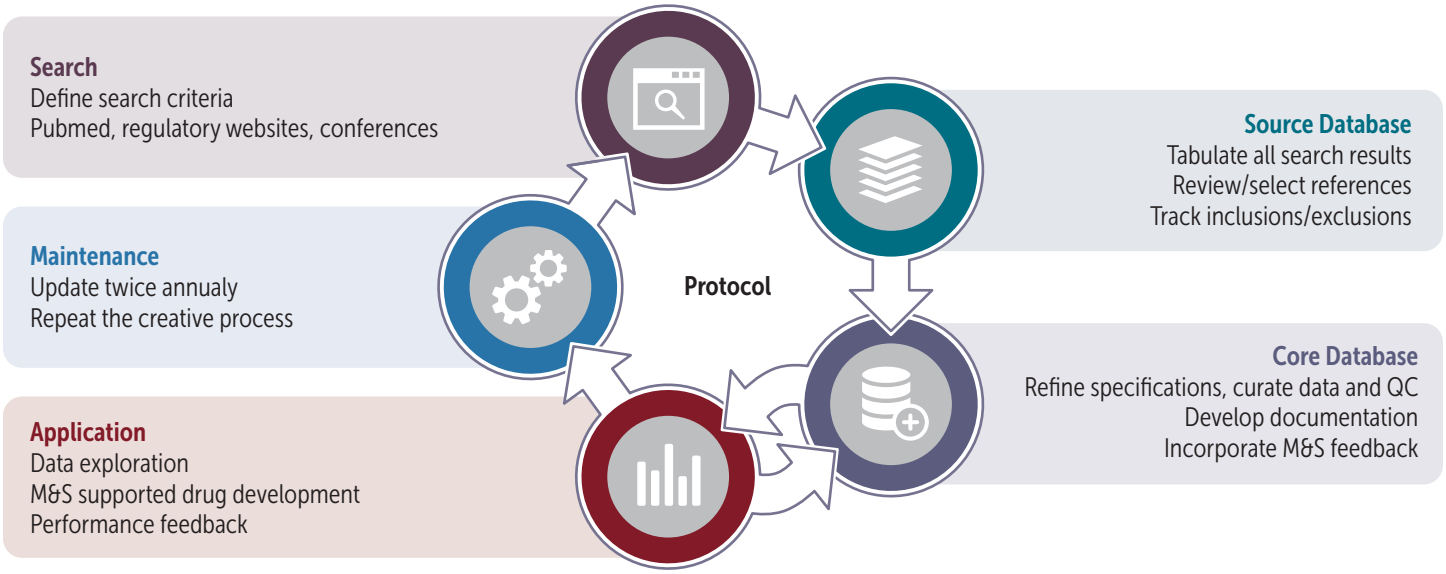
- **Comprehensive:** includes information for marketed drugs; data sources include journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separate source database and linked to unique clinical trial names
- **Flexibility:**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

The primary data sources were controlled clinical trials published in the medical literature. 40 references were identified and documented in the source database. The detailed reference information is recorded. Additional data, including data not published in journals, were obtained from FDA Summary Basis of Approval.

Outcome Fields

The clinical outcomes database contains information from 32 trials, representing 71 unique treatment arms and about 7,405 patients. There are a total of 3,138 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
ambrisentan	1	1	330
azathioprine	1	1	14
bosentan	2	2	481
bromhexine hydrochloride	1	1	15
co-trimoxazole	1	1	95
colchicine	3	3	39
etanercept	1	1	46
everolimus	1	1	44
ifn gamma	6	6	778
imatinib	1	1	60
macitentan	1	1	119
n-acetylcysteine	4	4	291
nintedanib	3	6	981
no treatment	2	2	58
pirfenidone	5	7	949
placebo	26	26	2903
prednisone	1	1	12
prm-151	1	3	15
sildenafil	2	2	103
warfarin	1	1	72
TOTAL	**32**	**71**	**7405**

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

endpoint	trials	arms	patients
6mwd	16	34	3783
6mwd decrease	3	6	1247
acute exacerbation	12	25	3841
acute exacerbation rate	1	5	428
ae any	18	43	5208
ae gi	10	23	2908
ae hepatic	1	2	616
ae respiratory	4	8	1206
ae serious	16	37	4911
alt elevation	5	10	2264
alt/ast elevation	6	15	2838
anorexia	6	14	1839
arthralgia	8	17	2963
ast elevation	5	10	2251
bronchitis	11	25	4720
cirrhosis	1	2	616
cough	8	18	2383
death	27	58	7047
death ipf	10	20	2113
desaturation	1	2	181
diarrhea	15	34	5082
disease progression	11	22	3308
dizziness	11	26	4221
dlco	15	34	4003
dlco alveolar	1	2	182
dlco decrease	1	2	89
dlco predicted	18	38	3412
dlco predicted decrease	1	2	27
dropout	10	20	2411
dropout ae	16	37	4234
dropout exacerbation	3	7	484
dropout pd	3	7	484
dyspnea	14	33	5081
dyspnea remission	1	2	178
dyspnea score	12	24	3302
dyspnea worsening	1	2	555
fatigue	14	34	4636
fev1	2	4	210
fev1 predicted	2	6	53
fvc	18	41	4991
fvc decrease	5	13	1354
fvc predicted	20	46	5177
fvc predicted decrease	5	10	1907
fvc rate	3	9	1489
ggt elevation	3	7	1595
hepatitis	1	2	616
hr death	7	14	2703
hr death ipf	1	2	555
hr disease progression	5	10	1370
hr fvc decrease	1	2	145
hr ipf worsening	1	2	616
hr os	1	2	27
hr pfs	3	6	1247
ipf worsening	7	17	2201
lft abnormal	5	10	1222
median ttp	1	2	89
nasopharyngitis	10	26	4107
nausea	15	34	5357
os	14	28	4303
os time	1	2	50
pa-ao2	6	15	1084

pa-ao2 decrease	1	2	27
pao2	8	20	1195
pfs	5	12	1939
photosensitivity	4	10	1163
pneumonia	8	16	2556
pulmonary function decline	1	2	494
rash	7	15	2513
respiratory failure	6	12	2036
respiratory hospitalization	1	2	494
rti	7	14	2045
rti lower	6	12	1907
rti upper	17	38	5768
sao2	4	8	326
sgrq	12	29	3808
sgrq responder	1	5	428
spo2	8	20	2710
time to ipf exacerbation	3	6	1231
tlc	5	14	1138
tlc decrease	1	2	89
tlc predicted	7	14	411
ttp	2	7	758
uti	5	11	1930
vc	4	12	994
vc predicted	2	4	212
vomiting	10	26	3995
weight decrease	6	12	2708
TOTAL	**32**	**71**	**7405**

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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