CERTARA

Quantify NSCLC-ALK Clinical Outcomes Database

Summary Information

The NSCLC ALK Quantify Clinical Outcomes Database contains data evaluating interventions for NSCLC ALK.

Table 1. Summary information

Parameter	Description
format	Excel or KEEP format
indications	nsclc
references	10
trials	7
trial.arms	9
patients	1,517
data.rows	617
interventions	
key efficacy endpoints	cr, orr, os, pfs, pfs median, pr, response duration
key safety endpoints	constipation, constipation grade 3 or 4, decreased appetite, decreased appetite grade 3 or 4, diarrhea, diarrhea grade 3 or 4, dropout ae, edema, elevated alt, elevated alt grade 3 or 4, elevated ast, fatigue, nausea, nausea grade 3 or 4, vomiting, vomiting grade 3 or 4

Features and benefits

Key Features

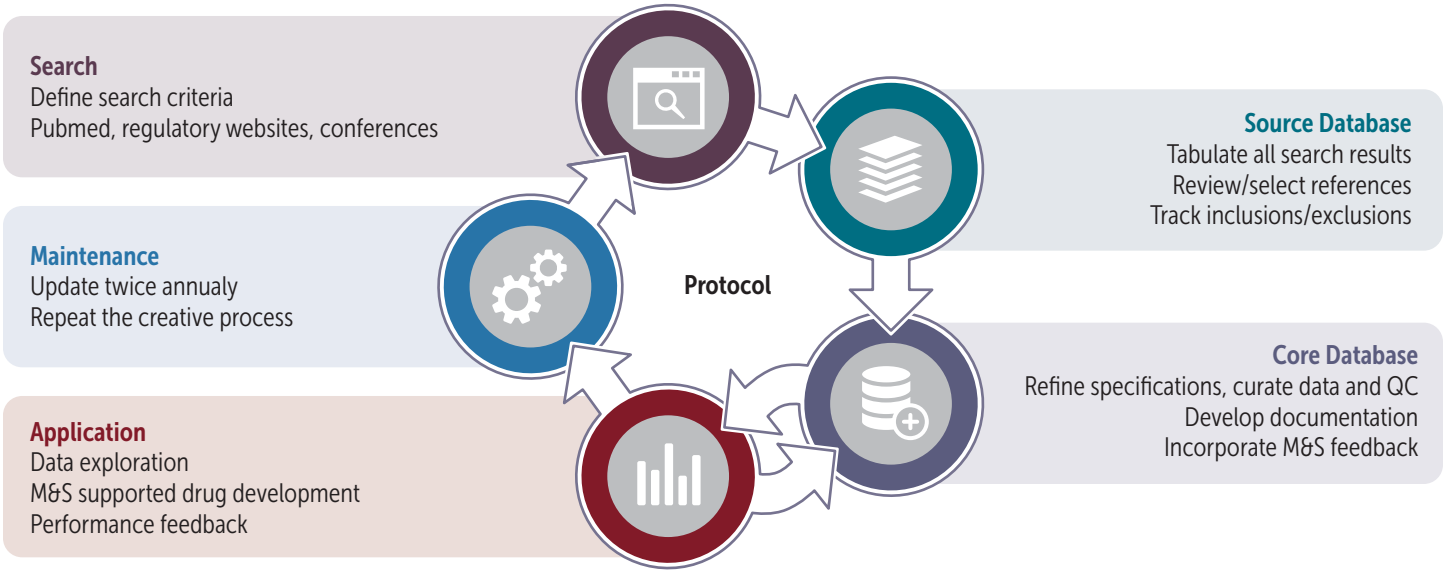
- **Comprehensive:** includes information for marketed drugs; data sources include journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separate source database and linked to unique clinical trial names
- **Flexibility:**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

The primary data sources were controlled clinical trials published in the medical literature. 10 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 7 trials, representing 9 unique treatment arms and about 1,517 patients. There are a total of 617 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. Class, number of trials, treatment arms and patients by drug

randomized.drug	class	trials	arms	patients
ap26113	alk	1	1	125
ceritinib	alk	1	1	246
ch5424802	alk	1	1	46
crizotinib	alk	4	4	755
pemetrexed|docetaxel	chemo	1	1	174
pemetrexed+cisplatin|carboplatin	chemo+chemo	1	1	171
TOTAL		**7**	**9**	**1517**

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
abdominal pain	ae	1	2	343
abdominal pain grade 3 or 4	ae	1	2	343
alopecia	ae	1	2	347
alopecia grade 3 or 4	ae	1	2	347
constipation	ae	6	8	1271
constipation grade 3 or 4	ae	4	6	885
cough	ae	1	1	125
cr	response	4	5	1003
cr irc	response	2	2	292
decreased appetite	ae	4	5	878
decreased appetite grade 3 or 4	ae	2	3	492
diarrhea	ae	5	7	1225
diarrhea grade 3 or 4	ae	3	5	839
dizziness	ae	3	4	757
dizziness grade 3 or 4	ae	2	3	496
dor	survival	1	1	246
dose reduction	ae	1	1	46
dropout	ae	1	2	347
dropout ae	ae	4	5	667
dysgeusia	ae	3	4	757
dysgeusia grade 3 or 4	ae	2	3	496
dyspnea	ae	2	3	472
dyspnea grade 3 or 4	ae	1	2	347
edema	ae	4	5	882
edema grade 3 or 4	ae	2	3	496
elevated alt	ae	4	5	803
elevated alt grade 3 or 4	ae	3	4	542
elevated ast	ae	4	4	581
elevated ast grade 3 or 4	ae	2	2	195
fatigue	ae	4	5	882
fatigue grade 3 or 4	ae	2	3	496
headache	ae	1	1	125
nausea	ae	6	8	1271
nausea grade 3 or 4	ae	4	6	885
neutropenia	ae	2	2	307
neutropenia grade 3 or 4	ae	1	1	46
orr	response	5	7	1346
orr irc	response	2	2	292
os	survival	4	6	1085
pd	response	3	4	854
pd irc	response	1	1	246
pfs	survival	4	6	1100

pfs median	survival	4	5	1003
pr	response	4	5	1003
pr irc	response	2	2	292
rash	ae	3	4	542
rash grade 3 or 4	ae	3	4	542
response duration	response	4	5	1003
sd	response	3	4	854
sd irc	response	2	2	292
stomatitis	ae	2	3	389
stomatitis grade 3 or 4	ae	2	3	389
uri	ae	1	2	347
uri grade 3 or 4	ae	1	2	347
visual effects	ae	3	4	757
visual effects grade 3 or 4	ae	2	3	496
vomiting	ae	5	7	1225
vomiting grade 3 or 4	ae	3	5	839
TOTAL		**7**	**9**	**1517**

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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