CERTARA

Quantify ALL Clinical Outcomes Database

Summary Information

The Quantify Acute Lymphoblastic Leukemia (ALL) Clinical Outcomes Database documents clinical efficacy information in infants, children, and adults following salvage treatment for relapsed/refractory patients.

Table 1. Summary information

Parameter	Description
format	Excel or KEEP format
indications	children all, adult all, infant all
population	1st or 2nd relapse, 1st or 2nd relapse or refractory, 1st or later relapse, 1st or later relapse or primary refractory, 1st or later relapse or refractory, 1st relapse, 1st relapse , 1st relapse or primary refractory, 2nd or later relapse or refractory, 2nd relapse, 2nd relapse or refractory , 3rd relapse, primary refractory
references	66
trials	65
trial.arms	72
patients	16,358
data.rows	4,597
treatments	chemotherapy + bmt, chemotherapy + sct, clofarabine, clofarabine + cytarabine, hyper-cvad, imatinab, inotuzumab, l-asparaginase, methotrexate, mixed regimen, supportive care, unspecified regimen
key.efficacy.endpoints	CR, PFS, DFS (disease free survival), EFS (event free survival), os

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

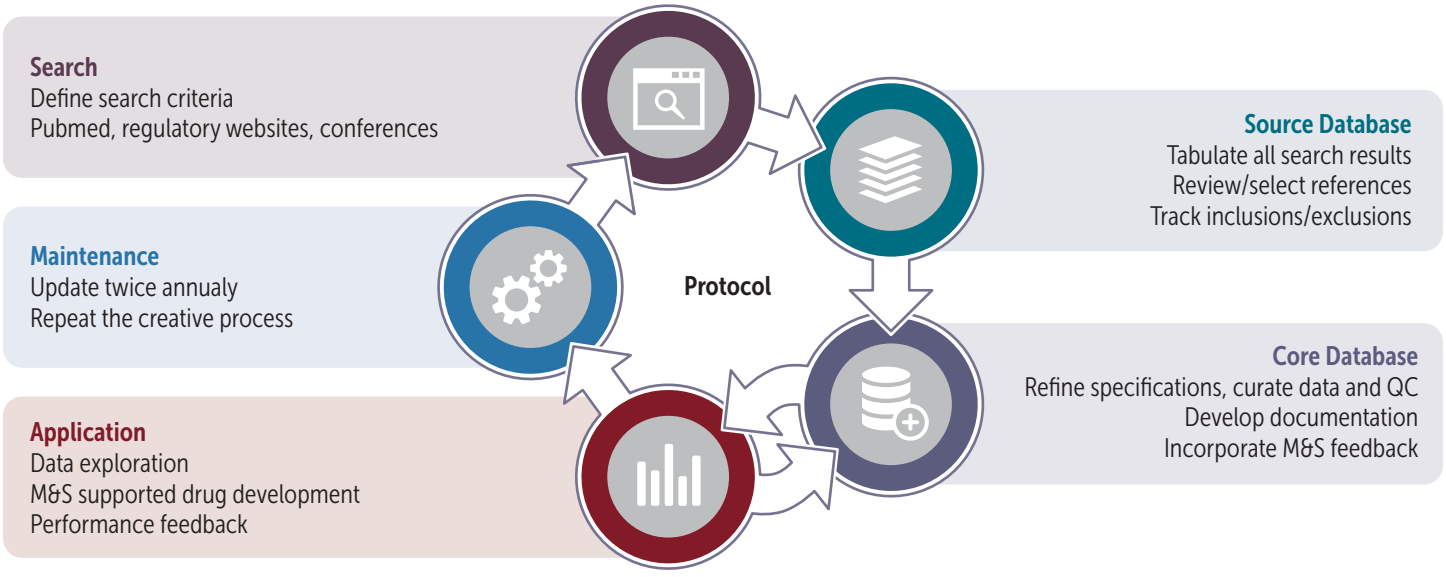
- **Model-friendliness:** designed and reviewed by experienced modelers to ensure highest quality and usability for modeling and simulation to support drug development strategies
- **Customizability:** can be augmented with clinical trial data proprietary to the client (this information goes into a separate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

The primary data sources were controlled clinical trials published in the medical literature. 66 references were selected to be included in the database. The detailed search results and review (inclusion/exclusion) information is recorded in the source database.

Outcome Fields

The clinical outcomes database contains information from 65 trials, representing 72 unique treatment arms and about 16,358 patients. There are a total of 4,597 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. Class, number of trials, treatment arms and patients by drug

randomized.drug	class	trials	arms	patients
chemotherapy + bmt	chemotherapy/transplantation	1	1	31
chemotherapy + sct	chemotherapy/transplantation	4	5	1066
clofarabine	chemotherapy	2	2	91
clofarabine + cytarabine	chemotherapy	2	2	57
hyper-cvad	chemotherapy	2	2	156
hyper-cvad	chemotherapy	1	1	66
imatinab	tyrosine kinase inhibitor	1	1	68
inotuzumab	anti-cd22	1	1	49
l-asparaginase	chemotherapy	1	2	147
methotrexate	chemotherapy	1	1	2732
mixed regimen	chemotherapy	50	53	10958
supportive care	supportive care	1	1	465
unspecified regimen	chemotherapy	1	1	134
TOTAL		**65**	**72**	**15954**

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
cr	response	51	56	7250
cr bm	response	1	1	68
cr total	response	1	1	68
cri	response	2	2	85
crp	response	4	4	230
dfs	survival	9	9	1737
efs	survival	25	28	3886
os	survival	44	49	12609
pfs	survival	1	2	212
response duration	survival	2	2	337
ttp	survival	1	1	68
TOTAL		**65**	**72**	**15954**

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.

For more information visit www.certara.com or email sales@certara.com.

DS Jun 2016 v2 111116