CERTARA

Quantify HBV Clinical Outcomes Database

Summary Information

The Quantify HBV Database is developed to document clinical safety and efficacy information on different nucleosides (eg, entecavir, lamivudine, tenofovir disoproxil fumarate, telbivudine, adefovir and combination) focusing on 3 different endpoints: HBV DNA time course, HBsAG time course, and HBeAG seroconversion that are available in the public domain.

Table 1. Summary information

Parameter	Description
format	Excel
indications	hbv
references	77
trials	66
trial arms	159
patients	14,133
data rows	2,095
compounds	adefovir, besifovir, entecavir, interferon alfa-2a, interferon alfa-2b, lamivudine, peginterferon alfa-2a, peginterferon alfa-2b, peginterferon lambda, placebo, telbivudine, tenofovir
key endpoints	alt, hbeag loss, hbeag seroconversion, hbsag, hbsag loss, hbsag seroconversion, hbv dna

Features and Benefits

Key Features:

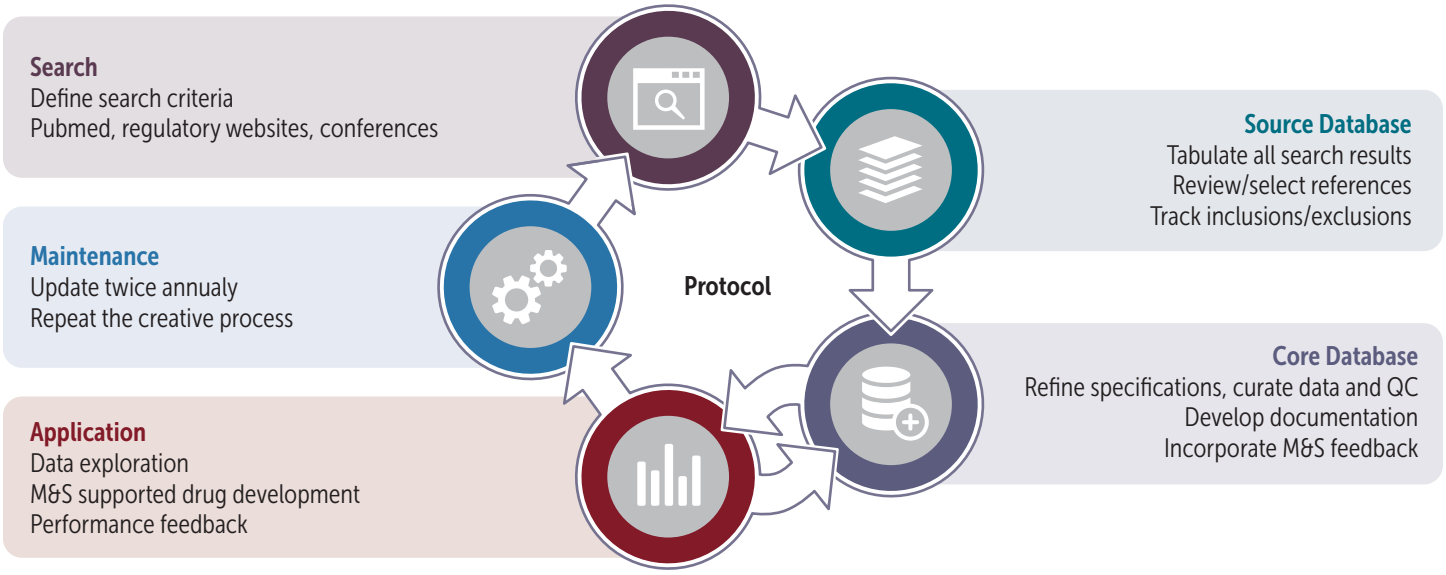
- **Comprehensive:** includes information for marketed drugs; data sources include journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separate source database and linked to unique clinical trial names
- **Flexibility:**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

The primary data sources were controlled clinical trials published in the medical literature. 77 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 66 trials, representing 159 unique treatment arms and about 14,133 patients. There are a total of 2,095 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
adefovir	9	9	690
adefovir+entecavir	1	1	32
adefovir+lamivudine	3	3	137
besifovir	1	2	76
entecavir	35	48	3463
entecavir+adefovir	3	4	264
entecavir+peginterferon alfa-2a	1	1	85
entecavir+placebo	1	1	22
entecavir+tenofovir	2	2	234
interferon alfa-2a	1	1	51
interferon alfa-2b	1	1	115
lamivudine	12	12	1775
lamivudine+adefovir	6	6	553
peginterferon alfa-2a	10	17	1486
peginterferon alfa-2a+adefovir	2	2	121
peginterferon alfa-2a+entecavir	1	1	95
peginterferon alfa-2a+lamivudine	4	4	653
peginterferon alfa-2a+placebo	3	3	346
peginterferon alfa-2a+ribavirin	1	1	68
peginterferon alfa-2a+thymosin alfa-1	1	1	26
peginterferon alfa-2b	5	7	1007
peginterferon alfa-2b+adefovir	1	1	30
peginterferon alfa-2b+lamivudine	2	2	240
peginterferon lambda	1	1	80
placebo	3	3	122
telbivudine	4	4	158
tenofovir	13	15	1616
tenofovir+emtricitabine	4	4	298
tenofovir+entecavir	1	1	52
tenofovir+peginterferon alfa-2a	1	2	370
tenofovir+placebo	4	4	289
TOTAL	**66**	**159**	**14554**

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
alt	12	26	3502
hbeag	4	10	641
hbeag loss	37	90	7762
hbeag seroconversion	46	112	9090
hbsag	6	15	2075
hbsag loss	27	63	7967
hbsag seroconversion	28	67	8768
hbv dna	60	144	12489
TOTAL	**66**	**159**	**52294**

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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