CERTARA

Quantify Osteoarthritis Pain Clinical Outcomes Database

Summary Information

The current version of the database includes clinical safety and efficacy information on treatment options currently approved or in development for osteoarthritis pain. The current version of the database includes information on all systemic pharmacological interventions. This includes mono and combination therapy with NSAIDs, acetaminophen, opioids, COX-2 inhibitors, norepinephrine reuptake inhibitors, anti-NGF, anti-epileptic drugs (AEDs), antidepressants, and muscle relaxants.

Table 1. Summary information

Parameter	Description
format	Excel
indication	chronic pain pain
number of trials	135
number of patients	85,000
compounds	acetaminophen, amtolmetin guacyl celecoxib, chondroitin, codeine, diclofenac, duloxetine, electroacupuncture, eltenac, etoricoxib fentanyl, glucosamine, hyaluronate, hydromorphone, ibuprofen, ketoprofen, lumiracoxib, meloxicam, morphine, nabumetone, naproxcinod, naproxen, nimesulide, oxycodone, oxymorphone, piroxicam, RO 15-8081, rofecoxib, tanezumab, tapentadol, tenoxicam, tramadol, valdecoxib, willow bark
key efficacy endpoints	american pain society patient outcome questionnaire, brief pain inventory, general activity, haq, lequense oa severity Index, mos sleep scale, pain intensity, pain relief, patient global assessment of disease status or activity, patient global assessment of response, patient global impression of change, physician global assessment of disease status or activity, physician global impression of change, rescue medication sf-36, sleep, womac
key safety endpoints	ae blood/chemistry, ae cardiovascular, ae gastrointestinal, ae general, ae liver, ae musculoskeletal, ae nervous system, ae nose/eye/ear/throat/respiratory, ae other, ae renal/urinary ae skin, dropout

Features and Benefits

Key Features:

- **Comprehensive:** includes information for marketed drugs as well as drugs in development; data source includes journal publications, conference posters, regulatory reviews, etc
- **Ease of tracking:** all clinical trial publications are listed in a separated 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)

Potential Applications – Supporting Model-based Meta-analysis:

Characterize relative (comparative) clinical safety and efficacy profile

- Analyze relative efficacy, safety and speed of onset among drugs, taking into account impact of titration and drop out, as well as various imputations methods (last observation carried forward, baseline carried forward, observed cases, etc)
- Estimate the difference in magnitude of changes in pain scores across drugs and mechanisms of action
- Analyze differences in speed of onset across drugs

Characterize endpoint-to-endpoint relationships

- Scale from different pain measurements
- Explore potential differences or similarities in dose response relationship for a particular drug or drug class

Ultimately, these analysis help drug companies to optimize trial design, improve trial outcomes, and strengthen product differentiation.

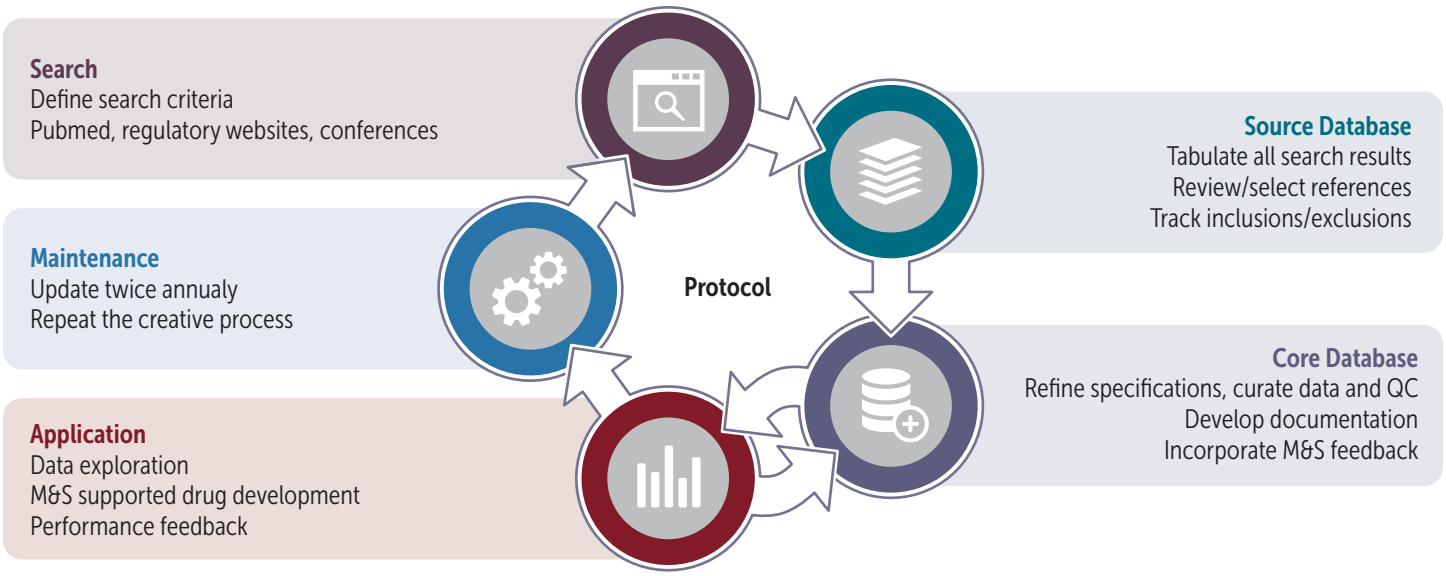
Why use our databases:

- Designed and managed by experienced modelers. There is a strong emphasis to making it easy to extract analysis datasets from the database
- Provide most relevant data to support clients' needs for quantitative decision making
- Contain 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 source database and the clinical outcomes database(core database), developed for osteoarthritis pain. The source database is a database that maintains the sources of information identified by searches and reviewed for inclusion or exclusion from the database. The clinical outcomes database contains the information on trial, treatment and patients characteristics and safety and efficacy results of the trials identified for inclusion in the database. In addition, a detailed documentation is provided with these databases.

The following is a flowchart showing the process with which databases are created, optimized and updated.



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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DS Feb 2017 v1 050117