

Quantify OS Clinical Outcomes Database



Summary Information

The Quantify Thrombosis in Orthopedic Surgery (TOS) Clinical Outcomes Database contains bleeding and VTE endpoint data from clinical trials investigating pharmaceutical interventions for preventing peri-operative thrombosis after orthopedic surgery of hip, knee, or both.

Table 1. Summary information

| Parameter | Description |
|------------------------|---|
| format | Excel or KEEP format |
| indications | surgery |
| references | 105 |
| trials | 108 |
| trial.arms | 334 |
| patients | 11,0063 |
| data.rows | 3,354 |
| compounds | acenocoumarol, apixaban, ardeparin, aspirin, bemiparin, betrixaban, certoparin, dabigatran, dalteparin, danaparoid, darexaban, desirudin, edoxaban, enoxaparin, fondaparinux, heparin, isis 416858, ly517717, nadroparin, no treatment, pd0348292, placebo, razaxaban, reviparin, rivaroxaban, semuloparin, sr123781a, tak442, tinzaparin, warfarin, ximelagatran |
| key efficacy endpoints | dvt, dvt distal, dvt distal all, dvt distal only, dvt proximal, dvt symptomatic, pe, pe fatal, pe non-fatal, vte, vte major, vte symptomatic |
| key safety endpoints | bleeding major, bleeding minor, bleeding non-major, bleeding relevant, bleeding total, death |

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

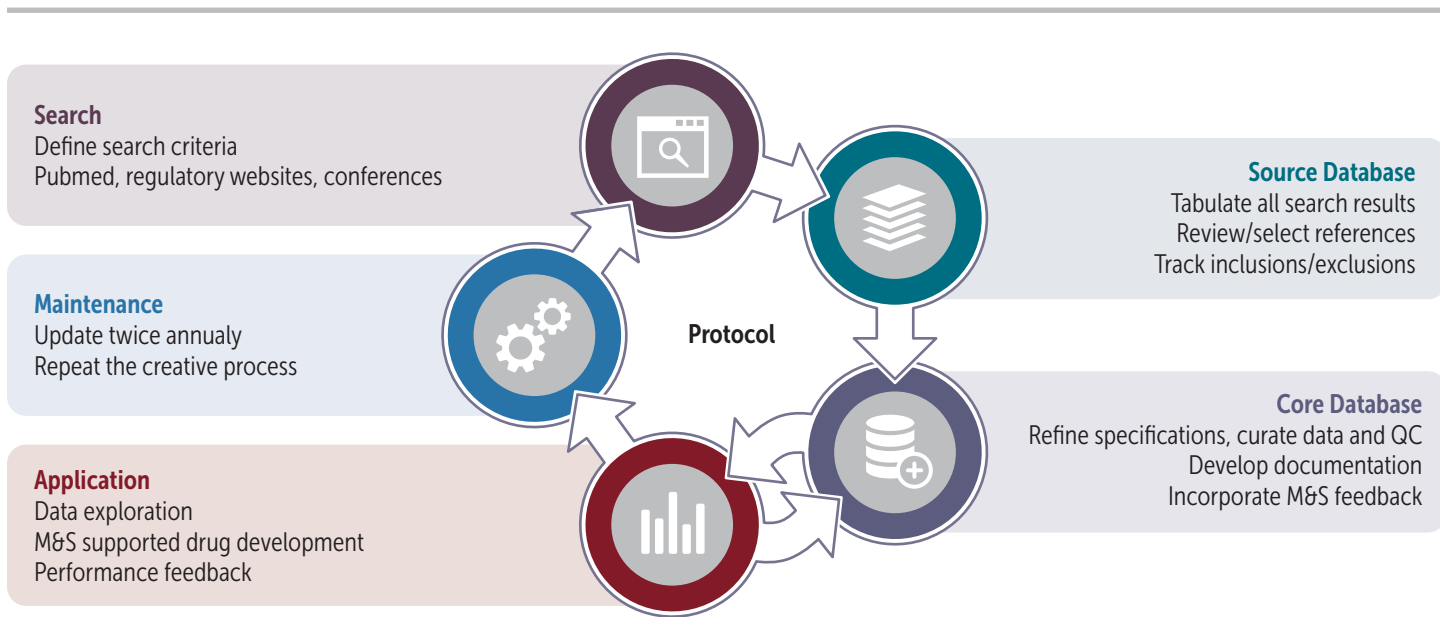
- **Model-friendliness:** designed and reviewed by experienced modelers to ensure highest quality and usability for modeling and simulation to support drug development strategies
- **Customizability:** can be augmented with clinical trial data proprietary to the client (this information goes into a separate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

The primary data sources were controlled clinical trials published in the medical literature. 105 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 108 trials, representing 334 unique treatment arms and about 110,063 patients. There are a total of 3,354 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. Number of trials, treatment arms and patients by drug

| randomized.drug | trials | arms | patients |
|-------------------------|------------|------------|---------------|
| acenocoumarol | 1 | 1 | 342 |
| apixaban | 4 | 9 | 6768 |
| ardeparin | 2 | 5 | 1324 |
| aspirin | 1 | 1 | 110 |
| bemiparin | 2 | 2 | 339 |
| betrixaban | 1 | 2 | 172 |
| certoparin | 1 | 2 | 341 |
| dabigatran | 7 | 23 | 8742 |
| dalteparin | 8 | 10 | 2086 |
| danaparoid | 3 | 3 | 503 |
| darexaban | 5 | 17 | 3044 |
| desirudin | 3 | 5 | 2110 |
| edoxaban | 6 | 13 | 2053 |
| enoxaparin | 70 | 79 | 36118 |
| fondaparinux | 7 | 15 | 7041 |
| heparin | 17 | 17 | 3343 |
| heparin+dhe | 3 | 3 | 296 |
| isis 416858 | 1 | 2 | 225 |
| ly517717 | 1 | 6 | 417 |
| nadroparin | 5 | 5 | 804 |
| no treatment | 2 | 2 | 101 |
| pd0348292 | 1 | 7 | 992 |
| placebo | 15 | 15 | 1453 |
| razaxaban | 1 | 4 | 506 |
| reviparin | 3 | 5 | 1296 |
| rivaroxaban | 8 | 25 | 7468 |
| semuloparin | 4 | 8 | 2807 |
| sr123781a | 1 | 5 | 854 |
| tak442 | 1 | 6 | 885 |
| tinzaparin | 4 | 5 | 1316 |
| warfarin | 13 | 13 | 6848 |
| ximelagatran | 5 | 9 | 4430 |
| ximelagatran+melagatran | 5 | 10 | 4929 |
| TOTAL | 108 | 334 | 110063 |

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 |
|--------------------|------------|------------|---------------|
| bleeding major | 90 | 291 | 101244 |
| bleeding minor | 67 | 227 | 81382 |
| bleeding non-major | 34 | 129 | 52246 |
| bleeding relevant | 15 | 46 | 24329 |
| bleeding total | 53 | 176 | 57948 |
| death | 61 | 181 | 61104 |
| dvt | 88 | 258 | 88957 |
| dvt distal | 6 | 24 | 4565 |
| dvt distal all | 21 | 64 | 23973 |
| dvt distal only | 76 | 224 | 80614 |
| dvt proximal | 89 | 276 | 90579 |
| dvt symptomatic | 28 | 87 | 37678 |
| pe | 87 | 268 | 86105 |
| pe fatal | 13 | 32 | 21057 |
| pe non-fatal | 18 | 46 | 33265 |
| vte | 83 | 272 | 92591 |
| vte major | 59 | 197 | 71791 |
| vte symptomatic | 20 | 71 | 33636 |
| TOTAL | 108 | 334 | 110063 |

About Certara

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