CERTARA

BROCHURE

CODEX Clinical Outcomes Databases

Highly Curated Clinical Trial Outcomes Data to Inform Critical Drug Development Decisions Earlier, with Confidence

Certara's Clinical Trial Outcomes Database (CODEX), consisting of publicly available clinical trial data for marketed drugs and drugs in development across 8 therapeutic areas and 60+ indications, is a comprehensive repository of structured and unstructured data, that can be downloaded and integrated with internal datasets for modeling and simulation. CODEX helps inform critical drug development decisions and offers benefits in several key areas:

- **Trial Population** – analyze clinical data to identify target populations for new studies.
- **Strategic study design and optimization** – refine sample size calculations to substantially reduce costs and increase success rates.
- **Comparative efficacy and safety** – review integrated summaries of safety and efficacy (ISS/ISE) for similar products to inform regulatory approval strategies.
- **Commercial viability** – run economic models to generate additional data points that can be used to demonstrate value to payers and in competitive pricing assessments.

Model-based meta-analysis (MBMA)

MBMA leverages CODEX databases and pharmacology models to increase drug development productivity, quantitatively inform portfolio management and improve clinical trial success. The key advantages of MBMA include optimization of trial design, e.g., features such as time, endpoints, and dosing, as well as competitive landscaping. MBMA supports bridging across studies, thereby enabling comparison of treatments and patient populations that may never have been tested together in the same clinical trial.

The extensive CODEX dataset library covers the following therapeutic areas:

- Oncology
- Immunology
- Cardiovascular
- Metabolic Disease
- Central Nervous System (CNS)
- Pain
- Respiratory
- Ophthalmology

Relapsed and Refractory Multiple Myeloma (RRMM) Database

~360 Studies

Key Response to treatment & Survival Endpoints (Complete, Partial & Stable responses, ORR , OS & PFS)

~40,000 Patients

All systemic or novel pharmacological treatments with primary focus on chemo & targeted therapy

~77,000

Longitudinal Data Points – Format available in Excel and CODEX (Clinical Outcomes Database Explorer)

Population Landscape

Relapsed and Refractory Multiple Myeloma [RRMM]

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A comprehensive repository of RRMM clinical outcomes

The CODEX Relapsed and Refractory Multiple Myeloma (RRMM) Database provides utility across the drug development continuum to inform critical decisions that determine not only a drug's successful performance during a trial, but also a drug's profile within a competitive landscape. The RRMM Database highlighted here is curated to document clinical efficacy and biomarker information from all randomized placebo and active controlled trials in Relapsed and Refractory Multiple Myeloma patients. Trials found in this database also include washout designs and add on designs.

CODEX RRMM database summary graphs

Table 1 - The top 11 drugs in the CODEX RRMM database

randomized.drug (top 11)	Class	Studies
pomalidomide+ dexamethasone	immunomodulator+ steroid	23
lenalidomide+ dexamethasone	immunomodulator+ steroid	13
thalidomide+ dexamethasone	immunomodulator+ steroid	11
bortezomib	proteasome inhibitor	10
thalidomide	immunomodulator	10
bortezomib+dexamethasone	proteasome inhibitor+steroid	9
carfilzomib+dexamethasone	proteasome inhibitor+steroid	8
daratumumab	anti-CD38	8
pomalidomide+ dexamethasone	immunomodulator steroid	23
bortezomib+dexamethasone	proteasome inhibitor+steroid	7
carfilzomib	proteasome inhibitor	7

Figure 1 - Snapshot of select treatments; OS time course

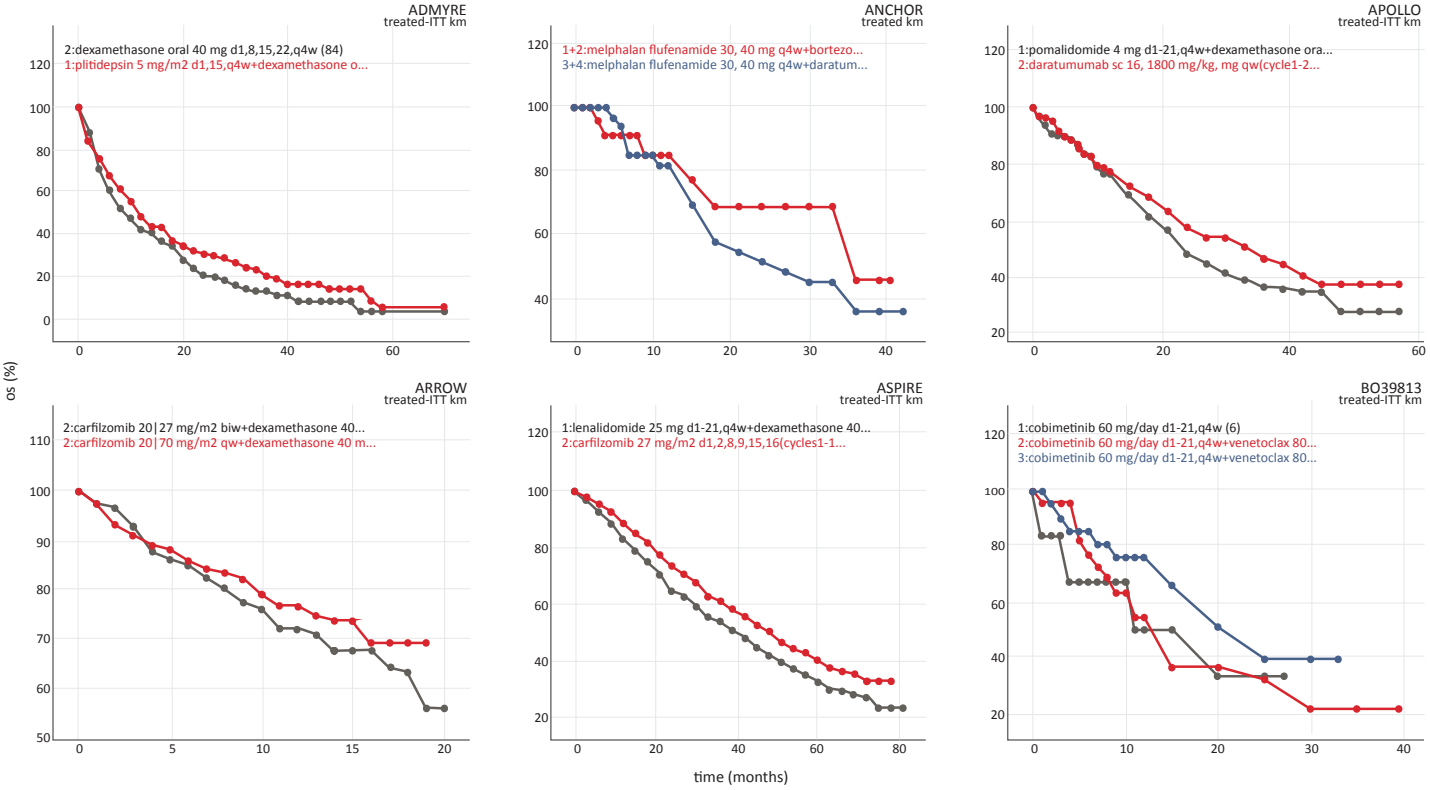
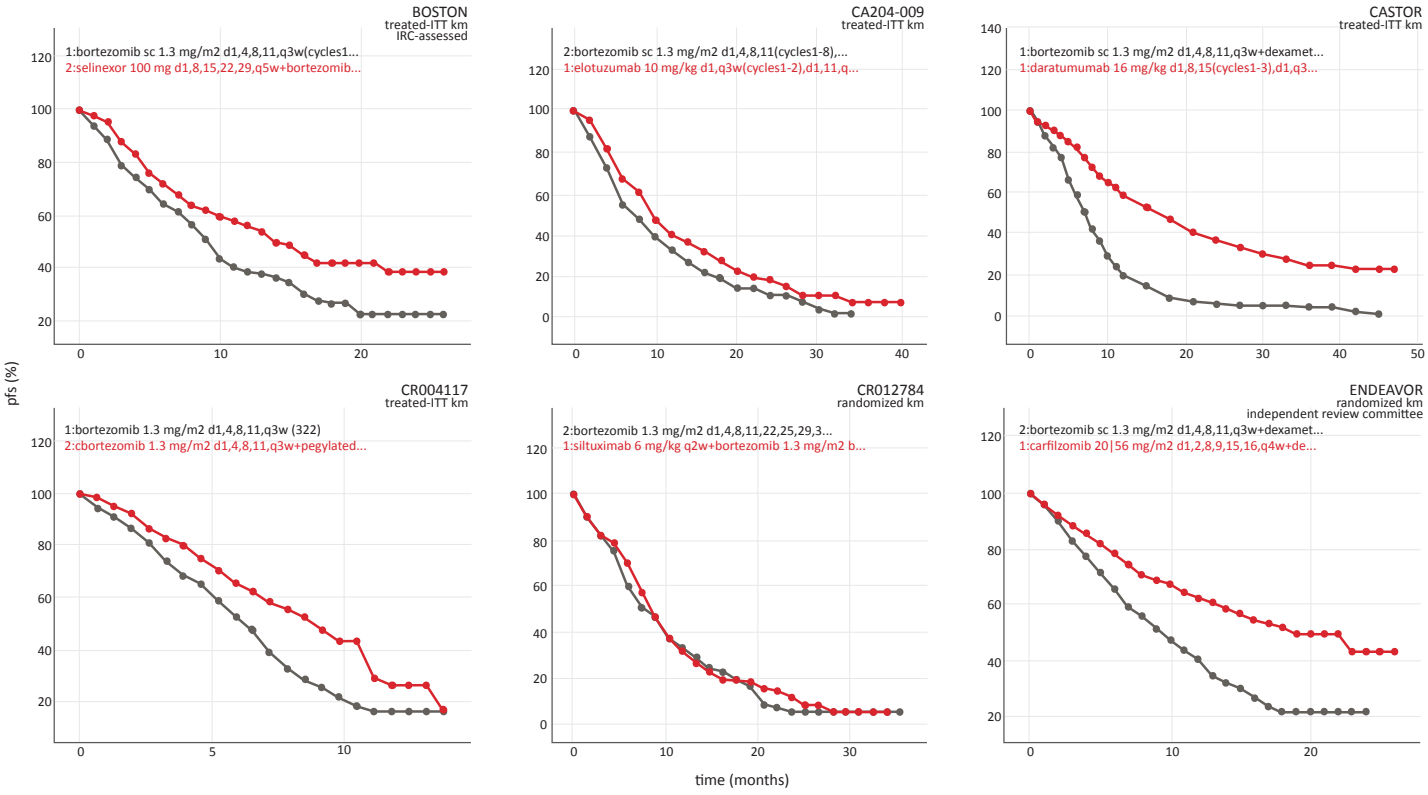


Figure 2 - PFS time course for trials with bortezomib



Email codexdb@certara.com to request a CODEX demo or more information.

About Certara

At Certara, we accelerate medicines to patients, partnering with life science innovators. Together we advance modern drug development with biosimulation, regulatory science, and market access solutions.

For more information visit certara.com