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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

Alzheimer's Disease (AD) Database

~354 Studies

Key Efficacy & Biomarker Endpoints (MMSE, ADAS-cog-11, NPI-12, CDR-sob, and ADCS-ADL-23)

~120,000 Patients

All systemic or novel pharmacological treatments with primary focus on disease modifying & Symptomatic treatments

~72,000

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

Population Landscape

Alzheimer's disease [AD] or Demensia

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A comprehensive repository of AD clinical outcomes

The CODEX Alzheimer's Disease (AD) 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 AD Database highlighted here is curated to document clinical efficacy and biomarker information from all randomized placebo and active controlled trials in Alzheimer's Disease patients. Trials found in this database also include washout designs and add on designs.

Table 1 - The top 9 drugs in the CODEX AD database

randomized.drug (top 9)	Class	Studies
donepezil	cholinesterase inhibitor	56
rivastigmine	cholinesterase inhibitor	35
memantine	NMDA inhibitor	26
galantamine	cholinesterase inhibitor	20
bapineuzumab	Abeta	12
rivastigmine	cholinesterase inhibitor	12
tacrine	cholinesterase inhibitor	12
solanezumab	Abeta	11
ponezumab	Abeta	9

CODEX AD database summary graphs

Figure 1 - Snapshot of select treatments; ADAS-cog-11 time course

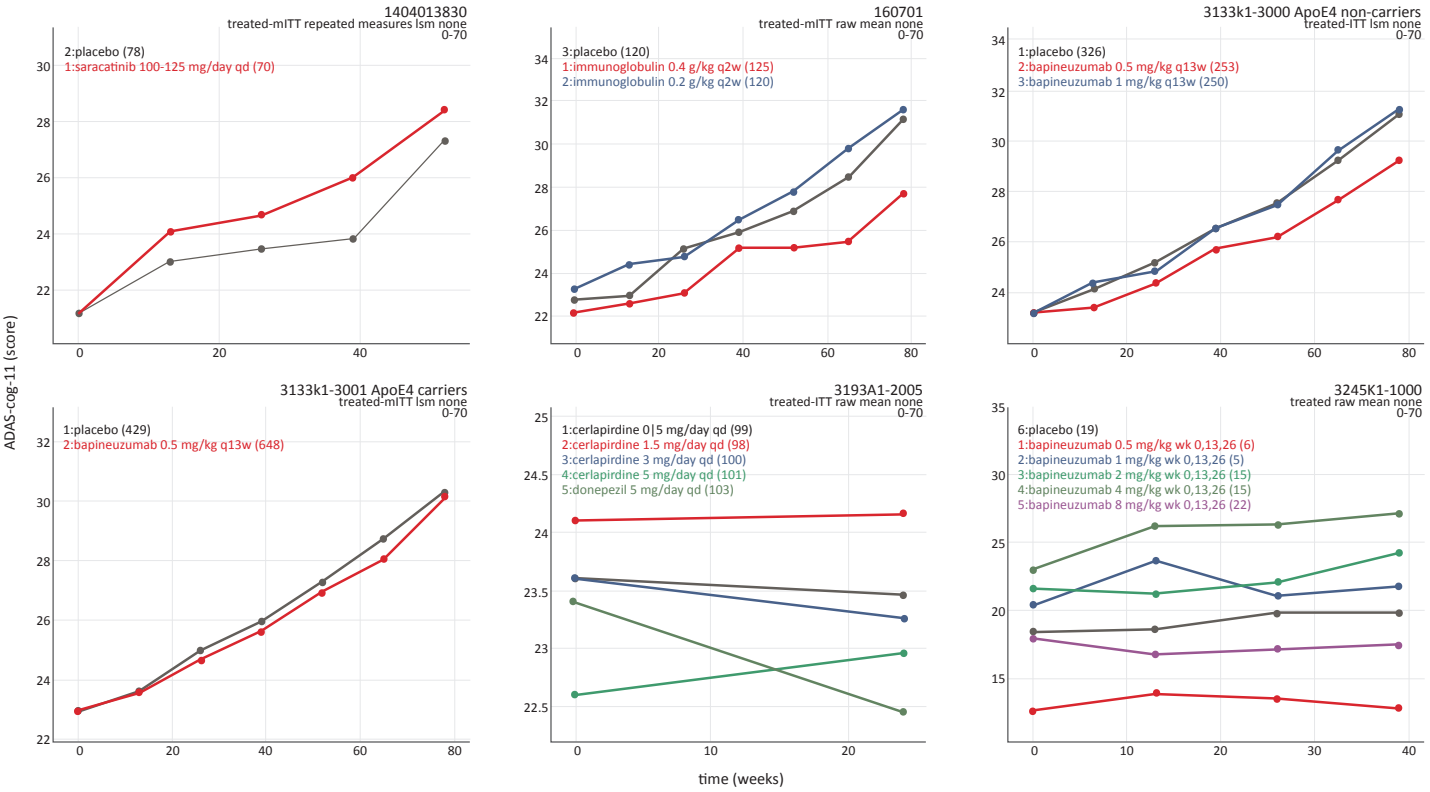
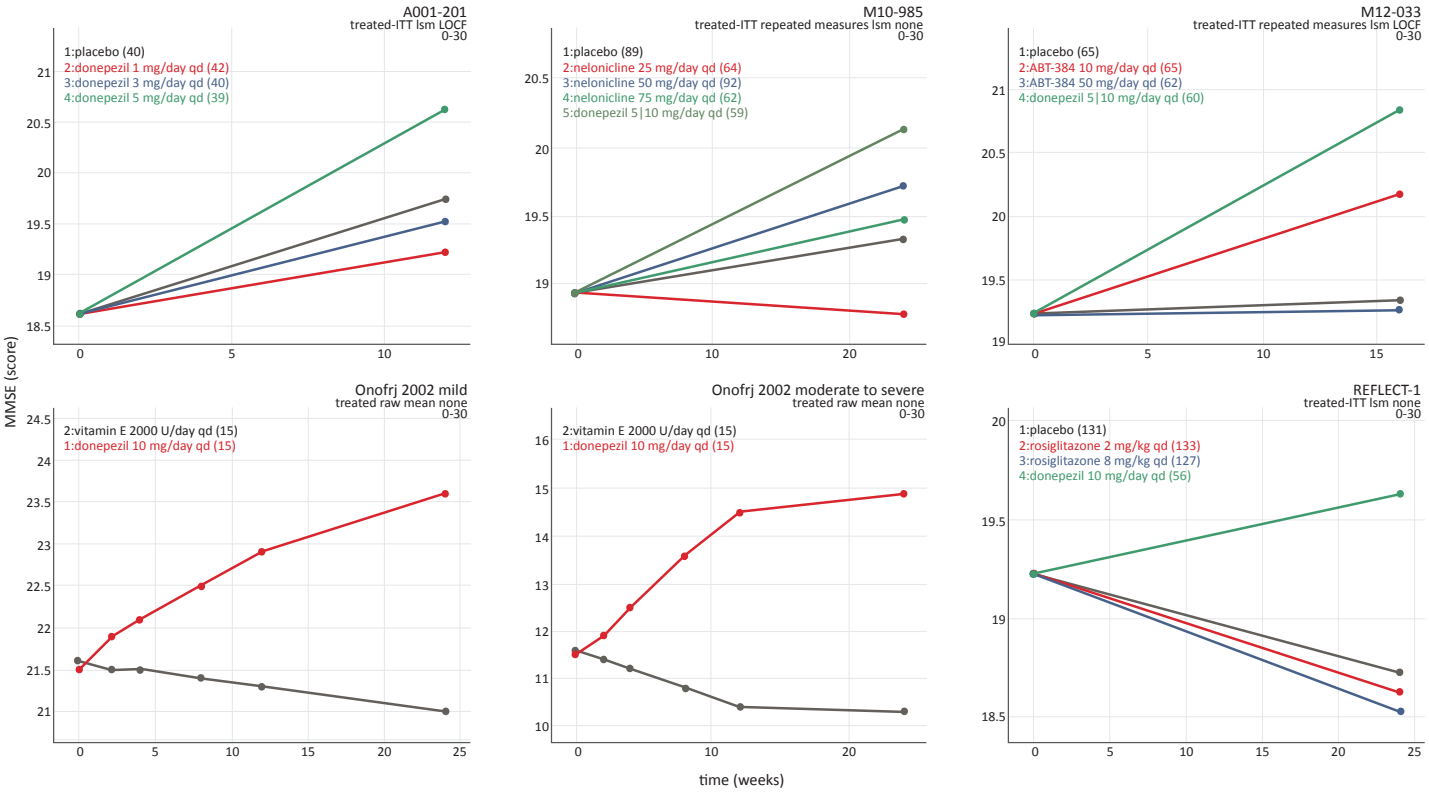


Figure 2 - MMSE time course for trials with donepezil



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