CERTARA^O

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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

Atopic Dermatitis (ADERM) Database



~136 Studies

Key Efficacy & Biomarker Endpoints (EASI, IGA, pruritus NRS, BSA, IgE, TARC, ALT and AST)



~35,000 Patients

All systemic or novel pharmacological treatments with primary focus on topical treatments



~80,000

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



Population Landscape

Atopic dermatitis [ADERM] or Eczema

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A comprehensive repository of ADERM clinical outcomes

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

CODEX ADERM database summary graphs

randomized.drug (top 9)	Class	Studies
dupilumab	anti-IL-4/13	21
baricitinib	JAK inhibitor	10
tralokinumab	anti-IL-13	10
abrocitinib	JAK inhibitor	9
lebrikizumab	anti-IL-13	9
crisaborole	PDE4 inhibitor	6
delgocitinib	JAK inhibitor	6
upadacitinib	JAK inhibitor	6
difamilast	PDE4 inhibitor	5

Figure 1 - Snapshot of select treatments; EASI time course





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Table 1 The top 9 drugs in the CODEX ADERM database



Figure 2 - EASI time course for trials with dupilumab











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

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