CERTARA

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

Psoriasis (PSO) Database

~328 Studies
Key Efficacy & Biomarker Endpoints (PASI75, PASI score, PASI90, DLQI)

~123,000 Patients
All systemic or novel pharmacological treatments with primary focus on biologics and synthetic DMARDs

~183,000
Longitudinal Data Points – Format available in Excel and CODEX (Clinical Outcomes Database Explorer)

Population Landscape
Psoriasis [PSO] or Psoriatic Arthritis [PsA]

A comprehensive repository of PSO clinical outcomes

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

Table 1 - The top 9 drugs in the CODEX PSO 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 PSO database summary graphs

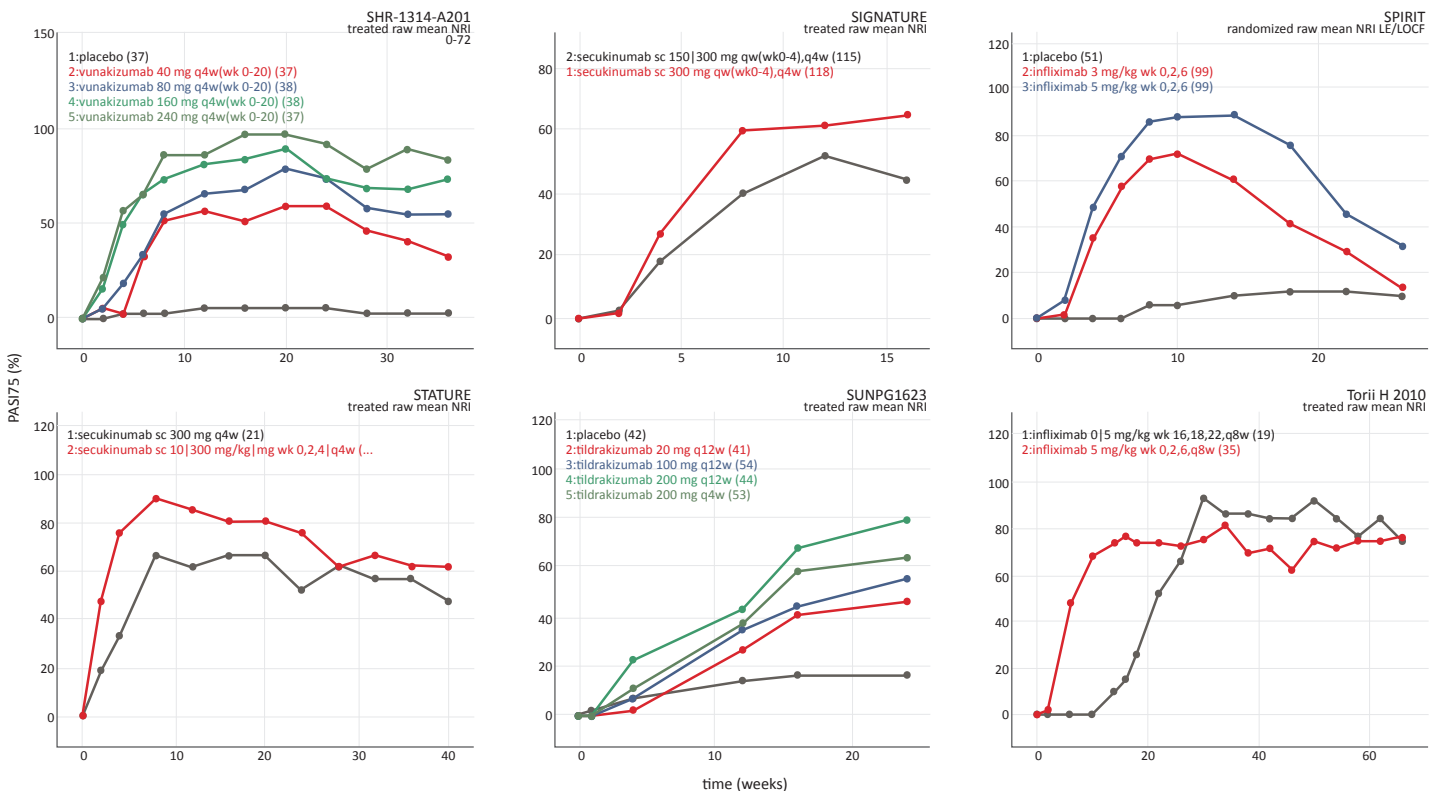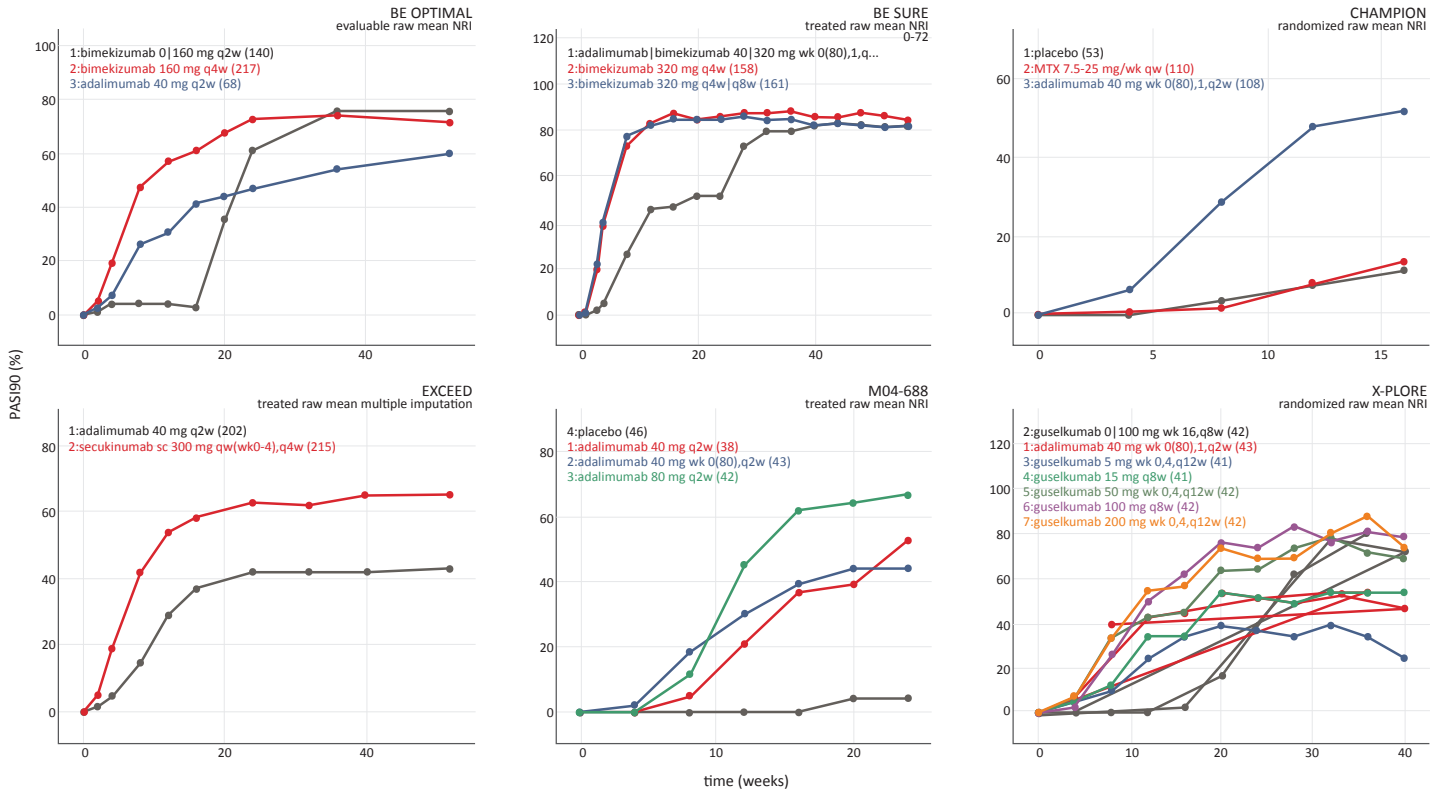**Figure 1** - Snapshot of select treatments; PASI75 time course

Figure 2 - PASI90 time course for trials with adalimumab

BE OPTIMAL
evaluable raw mean NRI
1:bimekizumab 0|160 mg q2w (140)
2:bimekizumab 160 mg q4w (217)
3:adalimumab 40 mg q2w (68)

BE SURE
treated raw mean NRI
0-72
1:adalimumab|bimekizumab 40|320 mg wk 0(80),1,q...
2:bimekizumab 320 mg q4w (158)
3:bimekizumab 320 mg q4w|q8w (161)

CHAMPION
randomized raw mean NRI
1:placebo (53)
2:MTX 7.5-25 mg/wk qw (110)
3:adalimumab 40 mg wk 0(80),1,q2w (108)

EXCEED
treated raw mean multiple imputation
1:adalimumab 40 mg q2w (202)
2:secukinumab sc 300 mg qw(wk0-4),q4w (215)

M04-688
treated raw mean NRI
4:placebo (46)
1:adalimumab 40 mg q2w (38)
2:adalimumab 40 mg wk 0(80),q2w (43)
3:adalimumab 80 mg q2w (42)

X-PLORE
randomized raw mean NRI
2:guselkumab 0|100 mg wk 16,q8w (42)
1:adalimumab 40 mg wk 0(80),1,q2w (43)
3:guselkumab 5 mg wk 0,4,q12w (41)
4:guselkumab 15 mg q8w (41)
5:guselkumab 50 mg wk 0,4,q12w (42)
6:guselkumab 100 mg q8w (42)
7:guselkumab 200 mg wk 0,4,q12w (42)

PASI90 (%)

time (weeks)

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