# Clinical Trial Outcomes Database Services

Excelra's Clinical Trial Outcomes Database (CTOD) supports clinical trial design optimization by providing intelligent data driven insights that empower informed decision making.

We offer our global Biotech and Pharma clients, customized indication-specific and/or drug-specific summary level databases, organized using PK/PD, clinical efficacy and safety outcomes data from clinical literature. We also offer on-demand user friendly Shiny applications to explore CTOD with dynamic dashboard generation.

## Informed Trial Design Optimization Using CTOD

- Right endpoint to track efficacy
- Right population for the trial
- Optimal duration (Safety vs. Efficacy)
- Right dose insights

## Clinical Trial Outcomes Database Scope

### Unlocking insights from clinical trial literature

Published clinical trial data is a goldmine of aggregated knowledge. Excelra's Clinical Trial Outcomes Database has been meticulously curated with our 15+ years' experience in extracting, analysing and harmonizing publicly available clinical trial information into analysis-ready datasets for Model-Based Meta-Analysis (MBMA), NONMEM and other statistical techniques. With regular data updates, CTOD provides extensive data coverage across major therapeutic areas and their associated drug, disease and clinical trial intelligence.

**Literature**

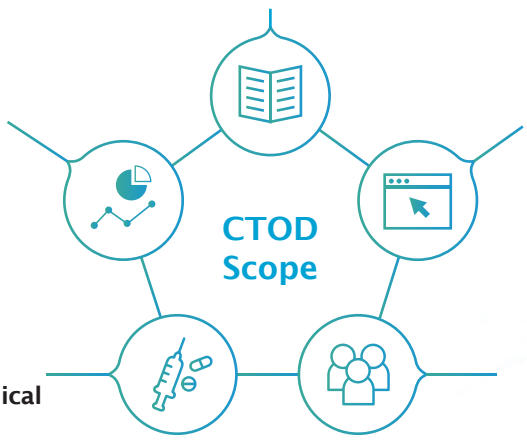
- Manuscript Details
- Data Source Details
- Link to Article
- Direct Link (DOI)

**Pharmacodynamics**

- Efficacy Outcomes
- Biomaker Outcomes
- Clinical Outcomes
- Progression Outcomes
- Quality of Life Outcomes
- Safety & Tolerability Outcomes

**Study Design**

- Trial Design
- Registry Details
- Clinical Phase
- Randomization & Control Flags
- Inclusion Criteria
- Exclusion Criteria




**Interventions**

**Pharmalogical Rx**

- Planned Treatment
- Actual Treatment
- Dossage Regimen
- Dossage Schedule

**Non-Pharmalogical interventions**

- Behavioural Modifications
- Lifestyle Modifications
- Rescue Modifications
- Diet
- Exercise

**Patient Demographics**

- Patient Covariates
- Medical Histories
- Concomitanta Conditions
- Prior Therapies
- Sub Groups
- Stratifications
- Baseline Biomaker Levels

# CTOD in Numbers

| >100 | 11 | >15k |
|---|---|---|
| Diseases areas | Therapeutic areas | Clinical Trials |

| |
|---|
| **Autoimmune** – 11 DAs, 1500+ trials |
| **Cardiovascular** – 8 DAs, 800+ trials |
| **Genitourinary** – 5 DAs, 500+ trials |
| **Infections** – 5 DAs, 500+ trials |
| **Metabolic** – 4 DAs, 1000+ trials |
| **Neuroscience**– 19 DAs, 2500+ trials |
| **Oncology** – 32 DAs, 8000+ trials |
| **Opthalmology** – 4 DAs, 400+ trials |
| **Others** – 12 DAs, 1000+ trials |
| **Pain & Inflammation** – 4 DAs, 500+ trials |
| **Respiratory** – 2 DAs, 600+ trials |

## Range of Rx, Clinical & Safety Outcomes, Populations

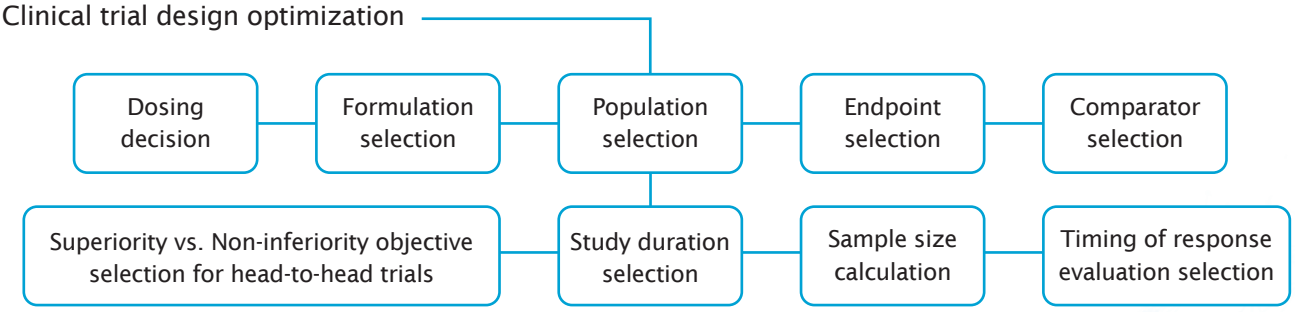
- ~1,000,000 patients
- Wide range ethnicities, age groups, populations
- >2000 unique treatments
- Multiple statistical populations
- >2 million records
- >200 million data points
- >1000 distinct efficacy outcomes
- Vast safety outcomes data

# CTOD Applications in Clinical Research

## Optimize & Accelerate Drug Development

CTOD comprises structured public source data on numerous clinical trial parameters including drug safety and efficacy, trial design and clinical outcomes. These analysis-ready datasets can be utilized to provide actionable insights that empower:

- Candidate selection
- Target selection
- Candidate development & Go/No-Go decisions
- Clinical trial design optimization




- Regulatory (Labelling)
- Comparative & effectiveness research
- Hypothesis generation for post-approval therapeutic optimization
- Link/scale biomarkers to clinical outcome
- Competitive intelligence
- Benchmarking

# CTOD Data Sources & Data Curation Process

## Best-in-class analysis ready data

Leveraging a techno-manual curation methodology, vast data from clinical trial literature is carefully structured around the evidence-based PICOS framework in CTOD. At Excelra, a rigorous 3-level Quality Control process is established to deliver best-in-class, high quality data with >99% accuracy proven in real-world analysis scenarios.

### Literature Sources

Summary Level / Patient Level Data

- Clinical Trial Registries
- Scientific Conference Abstracts
- Regulatory Reviews SBAs and EMEAs
- PubMed
- COCHRANE
- Proprietary Databases like EMBASE and IVOD
- Proprietary Information like CSRs

### Patient, problem or population

Who does the question relate to?

### Intervention

Can be a therapy, diagnostic test, prognostic factor, or issue

### Comparison

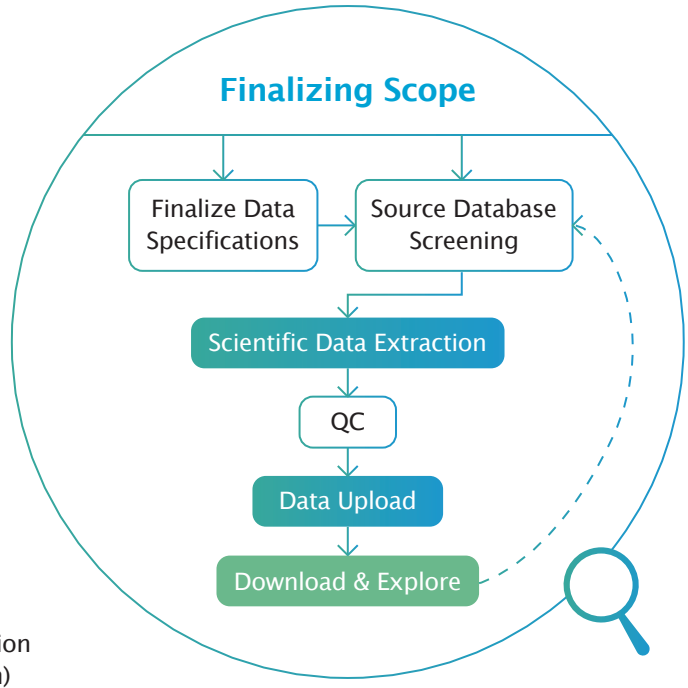
Can be another intervention, diagnostic test, placebo or usual (standard) care.

### Outcomes

Clearly sepcify the ones you are interested in, e.g. Reduction of pain, improved score on functional assessment, decreased length of hospital stay.

### Study designs

Decide on study designs best able to answer your question type (i.e., therapy, diagnostic  prognosis, etiologic, harm)




# The Excelra Edge

## The leading Clinical Pharmacology & Clinical Trial Outcomes Database services provider

We have successfully delivered 500+ customized databases to more than 25 top global Pharma and Biotech companies.

### Our Advantages

**>99% Accuracy**
High Quality is ensured with 3 level Quality Control (QC) process

**100+ Team of experts**
PharmD, MPharm and PhD

**15+ Years**
Extensive experience

**100+ Indications**
Across several therapeutic areas

**2-8 Week Quick turnaround**
90% of projects delivered

## You may also be interested in our allied custom curation offerings:

- Structuring disparate and heterogeneous data from preclinical/clinical reports
- On demand data support for Quantitative Structural Pharmacology (QSP) applications

**To know more, visit:** https://www.excelra.com/clinical/#clinical_trial

## About Excelra

Excelra's data and analytics solutions empower innovation in life sciences across the value chain from discovery to market. The Excelra Edge comes from a seamless amalgamation of proprietary curated data assets, deep domain expertise and data science. The company's multifaceted teams harmonize and analyze large volumes of disparate unstructured data using cutting-edge technologies. We galvanize data-driven decisions to unlock operational efficiencies to accelerate drug discovery and development. Over the past 18 years, Excelra has been the preferred data and analytics partner to over 90 global clients including 15 of the top 20 large Pharma companies.

marketing@excelra.com

www.excelra.com