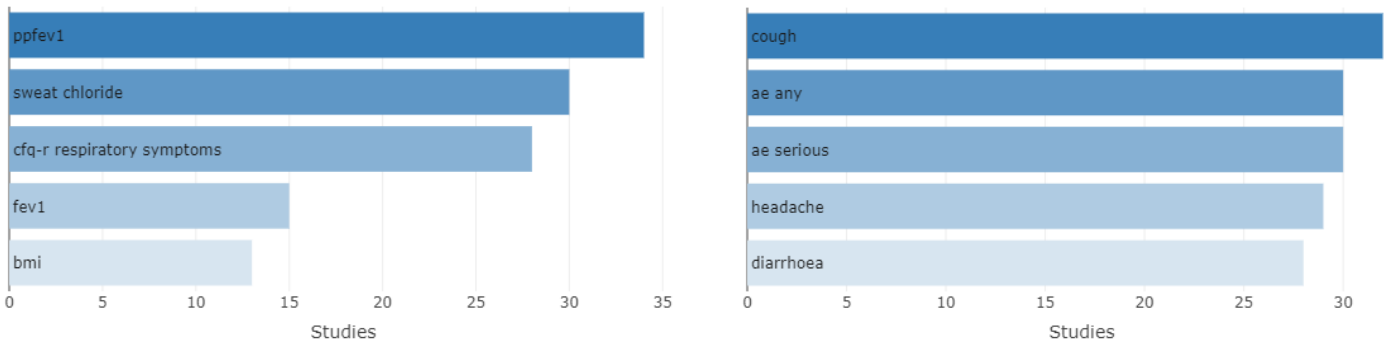
CODEx Cystic Fibrosis

The Cystic Fibrosis (CF) database

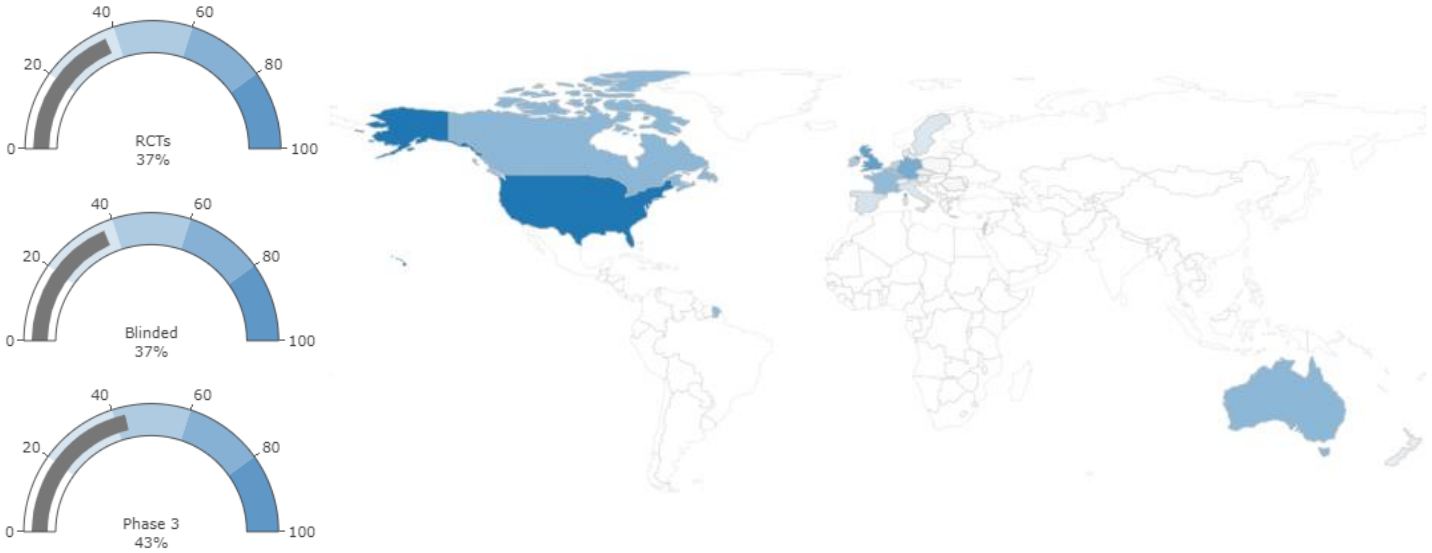
Content summary

The complete CODEx Cystic Fibrosis database contains summary level endpoint data from 35 studies reported in 38 references. The 5 most commonly reported efficacy endpoints are ppfev1 (34 studies), sweat chloride (30 studies), cfq-r respiratory symptoms (28 studies), fev1 (15 studies), and bmi (13 studies).



Evidence characteristics and global representation

Studies were conducted across the globe, with the majority in North America. A little more than 35% of the studies were blinded RCTs, and almost 45% of the studies were phase 3 trials.



About CODEx Clinical Outcomes Databases

The clinical evidence on drug efficacy and effectiveness is constantly expanding and it can be a challenge to keep track and visualize the clinical landscape. Certara's CODEx changes all that. CODEx is a smart combination of incredibly detailed databases and a state-of-the art exploratory tool to visualize the intricacies of literature data. This gives not only a wealth of information, but also the resources to maximize the value of the information.

Database features

The clinical outcomes databases are expressions of therapeutic landscapes of clinical research. They cover many therapeutic areas and are all structured and curated according to proprietary algorithms that give databases with unique benefits.

- Comprehensive: includes information on all marketed drugs within the scope of the database; data sources include citation databases, journal publications, conference posters, regulatory reviews, clinical trial repositories.
- Flexibility: the database design allows for quick updates as well as expansions to include additional indications/drugs/ endpoints/trials.
- Analysis-ready: Background treatments are categorized, missing covariates are imputed, endpoint data are calculated when applicable, and units are normalized.
- Customizability: databases can easily be expanded with in-house proprietary data.

Interface features

If the databases are like landscapes, the web-based CODEx interface is like the car that lets you explore these landscapes. The visualization tools allow you to navigate the landscape and get the maximum value from the data.

- Online access: the web-based portal makes sure you and your colleagues are always accessing the most up-to-date versions of the databases; no software installation required.
- User-friendly: users can explore and visualize data through a point-and-click interface that requires no knowledge of programming languages.
- Reactive: the database can be filtered on the fly, based on all relevant variables in the database, and all plots and tables react immediately to changes in data cuts.
- Interactive: state-of-the art tables and plots that can be interacted with – click, hover, and zoom to get more details.

The databases require the interface for exploration and downloads and the interface requires the databases to become functional. For this reason, we provide them together. Savvy analysts can use CODEx for initial explorations and can download specific data cuts at any time for analyses in their software of choice.

Applications

Exploring the clinical trial landscape

This can be very useful at initial stages of a trial design, either in the same therapeutic area or a related therapeutic area. Typical efficacy and safety endpoints, population characteristics and sample sizes, and design features can all be studied in a glance.

Understanding relative efficacy and safety profiles

This type of analysis is important and frequently done, especially for compounds in crowded markets. However, large trial-to-trial variations make direct numbers comparison less compelling and sometimes even meaningless. Clinical outcomes databases capture a broad range of trial-specific information, which enables comparative efficacy and safety analysis normalized by variables such as existing therapy, placebo response, patient characteristics, etc.

Linking different endpoints or indications

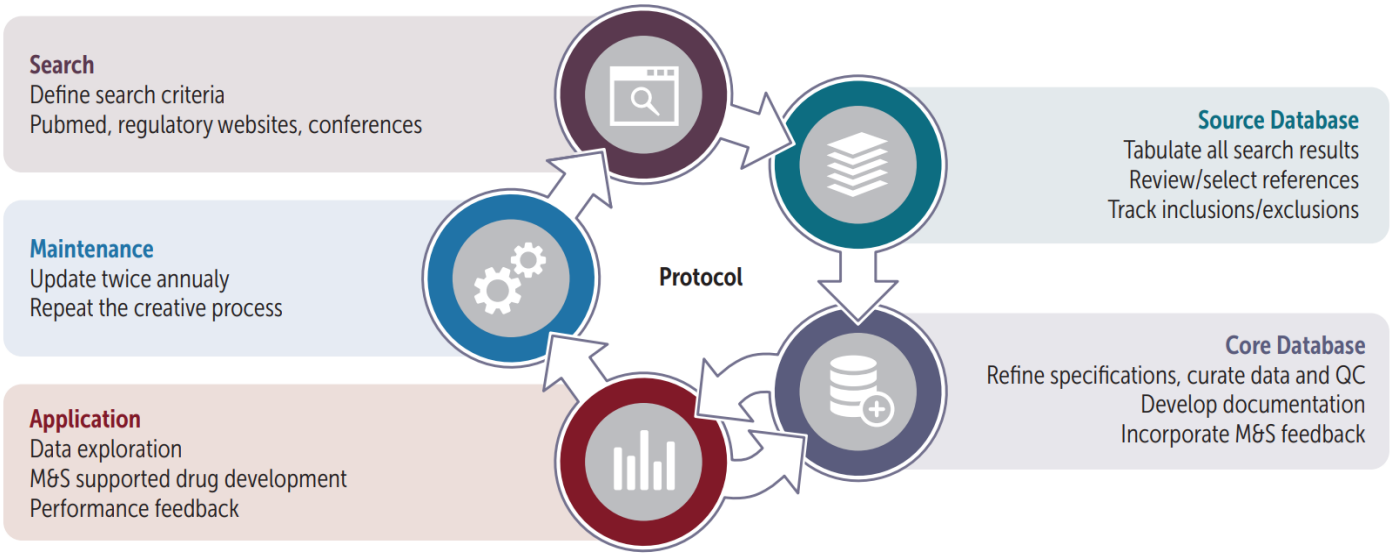
Clinical outcomes databases aggregate endpoint data from tens of thousands of patients, making it possible to make reasonable predictions of clinical outcomes from existing data. For example, clinical teams find it valuable to predict a compound's performance in late phase development based on early development results.

Brainstorming

At any stage of development, a good look at the evolving evidence of therapeutic efficacy and effectiveness by a team that consists of people with different perspective can be enlightening and bring out many ideas for optimizing next steps. PowerPoints and PDFs are typically poor tools to use in such sessions since they are static and plots and tables cannot be adjusted on the fly. With CODEx, you can create output based on any data cut in real time and

Structure and development

All databases are developed based on a strict protocol with search, selection, application, and maintenance steps. In the development process, we use two databases: one with citations only and one with clinical data. We make both available to you via the CODEx interface: you can not only download the core clinical outcomes database, but also the source database with all the references and citations. The following flowchart shows the process with which databases are created, optimized, and updated.



About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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