

Excelra社



Clinical Trial Outcome Databases

Excelra社のClinical Trial Outcome Databasesは主要な疾患に対する治験情報データベースです。医薬品開発データ解析コンサルタント会社であるQuantitativeSolutions (QS)と共同開発し、製薬企業様が治験薬の有効性および安全性の比較解析、バイオマーカーの変動と治験結果との相関解析及び治験結果の予測・改善を支援するように設計されており、開発中新薬の差別化戦略をバックアップします。Excelra社は医薬系データベースの開発における世界のリーディングカンパニーであり、医薬品研究開発を強固に支援致します。

疾患名 (DB名称)	# Referece	# Records
アルツハイマー病	129	8222
糖尿病	226	15622
NSCLC	150	3007
乳がん	147	3100
大腸がん	93	2328
胃がん	136	2190
膵臓がん	100	549
腎細胞がん	49	1010
脂質異常症	368	38693
C型肝炎	159	10675
神経疼痛	79	9083
骨粗鬆症	157	5396
リュウマチ	210	21574
統合失調症	166	13624
緑内障	89	3641
変形性関節症痛	151	12626
慢性腎臓疾患	51	2348
多発性硬化症	61	3867
慢性腰痛	48	5331

特徴

○網羅性：
開発中薬剤だけでなく市販薬の情報も含まれています。治験データの情報源としては、学術雑誌、学会ポスター、regulatory reviewなどがございます。

○追跡性：
治験情報刊行物がソースデータベースとして独立してリスト化されており、治験名称と一意に紐づけられています。

○モデル構築に適した構成：
メタ解析の専門知識を有する熟練したモデラーによる、新薬開発を支援するための高品質かつ高有用なモデリング&シミュレーションが可能なように設計されています。

左図に掲載されていない疾患の治験データにつきましては、Excelra社によるデータ収集サービスをご提供できます。また、QS社によるモデリング&シミュレーションのコンサルティングサービスを提供することもできます。

本データベースはソースデータベースとコアデータベースで構成されており、エクセルファイル形式で提供されます。

【a. ソースデータベース】 対象疾患における治験に関する情報源がまとめられています。

pmid	year	authors	title	journal	volume	pages	url	abstract
16395748	2006	Abe T, Takeuchi T, Miyasaka H, Hashimoto H, Kondo H, Kikawa Y and Nagaya I	A multicenter, double-blind, randomized, placebo controlled trial of infliximab combined with low dose methotrexate in Japanese patients with rheumatoid arthritis	J Rheumatol		33-37-44	http://www.ncbi.nlm.nih.gov/pubmed/16395748	OBJECTIVE: A placebo controlled, double-blind trial (DBT) was conducted for Jap (RA) despite treatment with low dose methotrexate (MTX) to evaluate the efficacy with infliximab was conducted in an open-label trial (OLT). METHODS: In the DBT treated with a placebo or 3 mg/kg or 10 mg/kg infliximab at Weeks 0, 2 and 6, co from the DBT received 3 mg/kg infliximab every 8 weeks. RESULTS: The mean D significantly more patients receiving 3 mg/kg (61.2%) and 10 mg/kg (52.9%) infliximab to the American College of Rheumatology (ACR) criteria at Week 14, compared to significant difference in incidence of adverse events among the treatment groups.
17985420	2007	Allaart CF, Breedveld FC and Dijkmans BA	Treatment of recent-onset rheumatoid arthritis: lessons from the BeSt study	J Rheumatol Suppl		80-25-33	http://www.ncbi.nlm.nih.gov/pubmed/17985420	OBJECTIVE: To determine the efficacy, toxicity, utilities, and costs of 4 treatment rheumatoid arthritis (RA). METHODS: 508 patients with recent-onset RA [r Health Assessment Questionnaire score 1-4] were randomized into 4 strategy groups to combination therapy: (1) initial combination therapy with methotrexate and sulfasalazine; (2) initial combination therapy with methotrexate and infliximab; (3) initial combination therapy with methotrexate and sulfasalazine; (4) initial combination therapy with MTX and infliximab. Treatment ad calculations of the DAS (target DAS < 2.4), by research nurses who were blinded data on treatment toxicity, functional ability, costs, and utilities. Yearly anonymiz
17083767	2006	Allaart CF, Goekoop-Ruiterman YP, de Vries-Bouwstra JK, Breedveld FC and Dijkmans BA	Aiming at low disease activity in rheumatoid arthritis with initial combination therapy or initial monotherapy strategies: the BeSt study	Clin Exp Rheumatol		24-5-77-82	http://www.ncbi.nlm.nih.gov/pubmed/17083767	AIM: To evaluate the efficacy and safety of four different treatment strategies for p (RA) METHODS: In the BeSt study, 508 patients with newly diagnosed (< 2 years according to four treatment strategies: 1. sequential monotherapy, 2. step up to c methotrexate), 3. initial combination therapy with methotrexate, sulfasalazine, s initial combination therapy with methotrexate and infliximab. These monthly therapy the Disease Activity Score (DAS), with the goal to achieve and maintain a DAS < every 3 months with the Health Assessment Questionnaire. Radiographs of hand; patient identity and treatment, and in random order, to measure joint damage pro
10589362	1999	Antoni C and Kalden JR	Combination therapy of the chimeric monoclonal anti-tumor necrosis factor alpha antibody (infliximab) with methotrexate in patients with rheumatoid arthritis	Clin Exp Rheumatol		17-573-7	http://www.ncbi.nlm.nih.gov/pubmed/10589362	Infliximab, a chimeric anti-TNF alpha antibody, showed in two double-blind placebo methotrexate (MTX) in patients with severe rheumatoid arthritis (RA). Whereas in compared to infliximab alone and in combination, the second trial compared inflix despite maximal tolerated MTX treatment. Infliximab showed synergistic effects of infliximab was reduced by the combination. Infliximab in combination with high-
15818699	2005	Kalden JR and Smolen J	Sustained benefits of infliximab therapy for dermatologic and articular manifestations of psoriatic arthritis: results from the infliximab multinational psoriatic arthritis controlled trial (IMPACT)	Arthritis Rheum		52-1227-36	http://www.ncbi.nlm.nih.gov/pubmed/15818699	OBJECTIVE: To investigate the efficacy and tolerability of infliximab therapy for the active psoriatic arthritis (PsA). METHODS: One hundred four patients with PsA ir modifying antirheumatic drug (DMARD) had failed were recruited into this investig blind, placebo-controlled clinical trial. During the initial blinded portion of the stud, mg/kg) or placebo at weeks 0, 2, 6, and 14. After week 16, patients initially assign infliximab 5 mg/kg every 8 weeks through week 50, while patients initially random treatment at the same dose through week 50. The primary efficacy outcome was Rheumatology 20% criteria for improvement in rheumatoid arthritis (ACR20) at the
10589361	1999	Bankhurst AD	Etanercept and methotrexate combination therapy	Clin Exp Rheumatol		17-569-72	http://www.ncbi.nlm.nih.gov/pubmed/10589361	Tumor necrosis factor (TNF) is a major proinflammatory cytokine in the rheumat administration of a recombinant version of its soluble p75 TNF receptor linked to t etanercept). The present study examined the combination of etanercept with met (rheumatoid arthritis (RA) who had persistent activity despite monotherapy with MT significantly better outcome than the placebo-MTX group using American College 71% of the patients in the etanercept-MTX group had an ACR 20% response (vers etanercept-MTX group, 39% had an ACR 50% response (versus 3% in the placeb

収録情報:

- Pubmed ID
- 文献情報 (出版年、著者、タイトル、文献名、巻号、ページ数、ウェブURL、,etc.

【b. コアデータベース】 治験情報がエクセル表にまとめられています。

Source Title	Source Authors	Source Journal	Source Volume	Source Pages	Source Year	Source Number	Source URL	Control	Name	Region	Location	Sponsor	Total Year	Total Primary	Arm	Randomized	ITT	Treat
1	Abe T, Takeuchi T, Miyasaka H, Hashimoto H, Kondo H, Kikawa Y and Nagaya I	Rheumatol	33	37-44	2006	93973	http://www.ncbi.nlm.nih.gov/pubmed/16395748	parallel		Japan	Centropo	2000	1	47				
2	Allaart CF, Breedveld FC and Dijkmans BA	J Rheumatol Suppl	80	25-33	2007	93974	http://www.ncbi.nlm.nih.gov/pubmed/17985420	parallel		Japan	Centropo	2000	1	47				
3	Allaart CF, Goekoop-Ruiterman YP, de Vries-Bouwstra JK, Breedveld FC and Dijkmans BA	Clin Exp Rheumatol	24	5-77-82	2006	93975	http://www.ncbi.nlm.nih.gov/pubmed/17083767	parallel		Japan	Centropo	2000	1	47				
4	Antoni C and Kalden JR	Clin Exp Rheumatol	17	573-7	1999	93976	http://www.ncbi.nlm.nih.gov/pubmed/10589362	parallel		Japan	Centropo	2000	1	47				
5	Kalden JR and Smolen J	Arthritis Rheum	52	1227-36	2005	93977	http://www.ncbi.nlm.nih.gov/pubmed/15818699	parallel		Japan	Centropo	2000	1	47				
6	Bankhurst AD	Clin Exp Rheumatol	17	569-72	1999	93978	http://www.ncbi.nlm.nih.gov/pubmed/10589361	parallel		Japan	Centropo	2000	1	47				

収録情報:

- 文献情報 (文献名、URLなど)
- 試験情報 (国、人種、会社名など)
- 治療情報 (投与薬名、投与方法など)
- 結果情報 (有効性、副作用情報など)
- 患者情報 (患者数、患者背景など)