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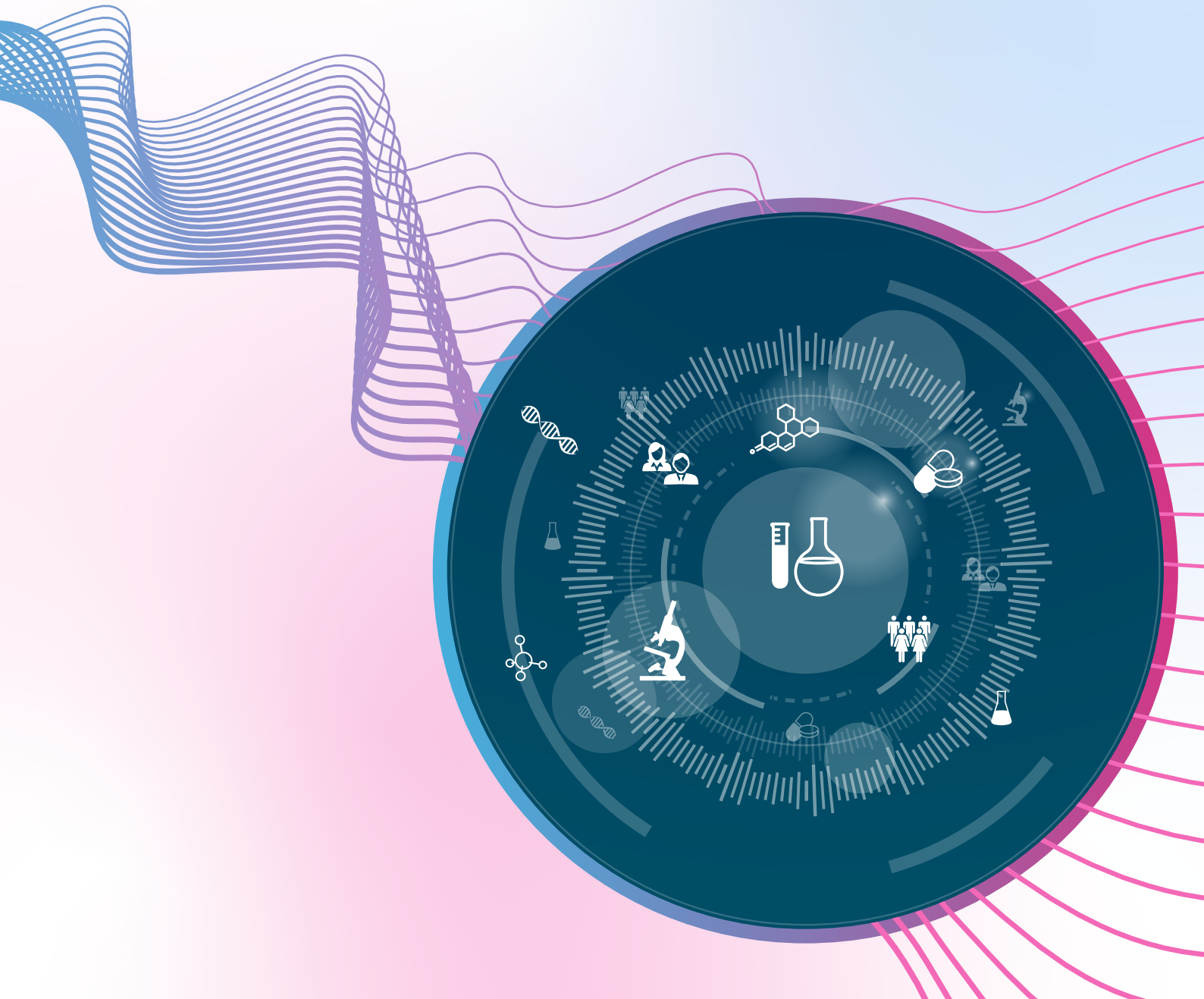
# Data driven competitive landscape analysis to facilitate go/no-go decision in clinical development

CASE STUDY



## Client

A Switzerland based large pharma company engaged in development of novel antibody therapeutics against rheumatoid arthritis (RA), was analysing the data to demonstrate the advantage of longitudinal meta-analysis over conventional meta-analysis that uses end-of-study (EOS) data, toward facilitating more effective model informed drug development (MIDD) decisions.

## Objective

The objective of the analysis was to determine the competitive position of their novel antibody in early clinical Phase II B versus all the approved biologics against rheumatoid arthritis (RA). They were mainly interested in performing a quantitative assessment of the longitudinal time course of clinical efficacy that would enable informed decision making on further clinical development.

## Requirement

The client approached excelra to develop a model based meta analysis (MBMA)-ready dataset, by curating all the existing scientific evidence around the efficacy of marketed biologics for RA.

- The curated dataset should have summary time-course response on clinical outcomes used in late stage clinical trials
- The data should also cover information about prior and concomitant medications including:
  - Respective category-wise percentage of patients (with response status to medications)
  - Baseline patient characteristics and sample size including N in statistical analysis

## Indication Background – Rheumatoid Arthritis

RA is an auto-immune disease that leads to inflammation, progressive joint damage, and disability. Therapeutic options range from corticosteroids, nonsteroidal anti-inflammatory drugs, analgesics, traditional disease modifying antirheumatic drugs (DMARDs), and then biologics.

Besides the fact that clinical effects of a drug depend on patient characteristics and the nature of prior and concomitant therapies; the 'speed of onset' of drug effect is important in RA because of the availability of multiple therapeutic options. In this regard, biologics are usually employed as the therapeutic choice for refractory patients (to DMARDs).

## Our approach

In line with the specified requirements, Excelra's Clinical Pharmacology group used a robust scientific curation methodology coupled with systematic literature review (SLR), to synthesize data on existing therapeutics for performing model based meta-analysis (MBMA). The following steps were implemented:

- Defined project scope with PICOS methodology for conducting Systematic Literature Review in PubMed.
- Screened, labelled and developed a database for enabling further qualification and selection of relevant publications according to PICOS specifications.
- Additional references were identified following a thorough search across FDA drug labelling information and traditional meta-analysis publications (119 sources identified).
- A customized clinical outcomes database was developed, capturing:
  - Clinical outcomes summary data (Time vs Response)
  - Patient population details (Baseline characteristics, prior and concomitant therapy)
  - Interventions (Dose regimen)
  - Comparator (Dose regimen)
  - Study design (Sample size)
- A rigorous 3-level Quality Control (QC) process was employed for database development.

**Table 1: Summary-level information about the studies included in the analysis**

| Drug name | No. of studies[1] | No. of patients[2] |
|---|---|---|
| Abatacept | 4 | 951 |
| Adalimumab | 7 | 1,403 |
| Anakinra | 1 | 250 |
| Certolizumab | 2 | 639 |
| Etanercept | 7 | 1,021 |
| Golimumab | 3 | 401 |
| Infliximab | 5 | 994 |
| Rituximab | 5 | 1,525 |
| Tocilitzumab | 29 | 5,287 |
| Methotrexate | 6 | 321 |
| Placebo | 4 | 683 |

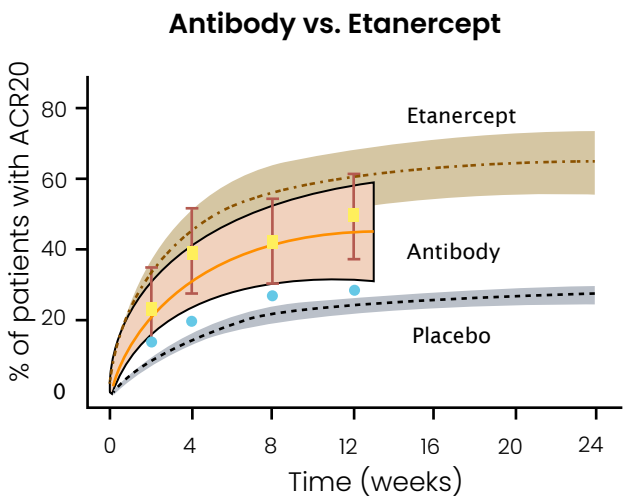
**Notes**

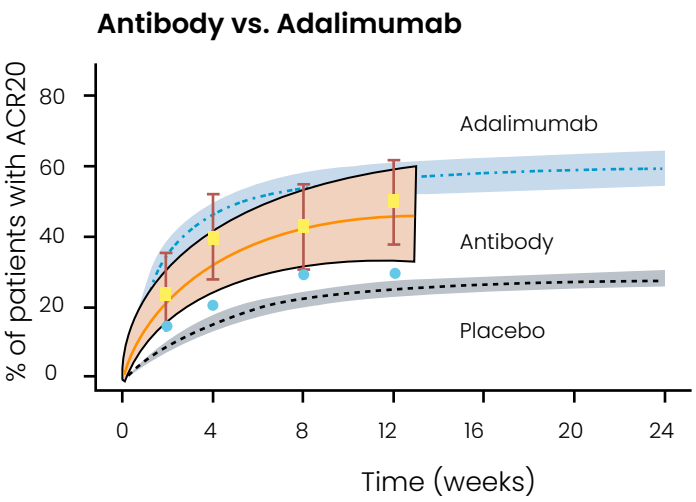
1 No. of studies with the corresponding drug

2 No. of patients receiving an approved dose of the corresponding treatment

## Outcomes

- Excelra refined the in-house literature database (Clinical Trial outcomes Database) for Rheumatoid Arthritis, which included 37 Phase II & III studies describing 13474 patients, 75 arms, and 502 summary points.
- The database was updated with each time-point, which was data-digitized from the illustrative time course curve from each study.
- This enabled the client to compare the antibody of interest with the available biologics for Rheumatoid Arthritis.
- The magnitude of response and the associated time course analysis from Excelra's databases showed that the novel antibody had lower chances of success owing to its inferior efficacy profile in RA (ACR20), when compared to competitor drugs, Etanercept and Adalimumab (as shown in figure below).




## Our approach

Based on the custom datasets developed by Excelra, the client was able to demonstrate the advantage of longitudinal data analysis over conventional EOS meta-analysis. Combining the resultant longitudinal MBMA on late stage clinical outcome ACR20, with inhouse Phase II B data of the novel antibody, helped the client to make a well-informed, data-driven 'No-Go' decision for further clinical development of the biologic against RA.

## Our service portfolio

Data

**Data curation**
Filter out the noise, focus your attention

**Clinical data**
Analysis-ready data for informed clinical decision-making

**Semantic data**
Refine your decisions, find your value

Insights

**Bioinformatics**
Illuminating the path to faster discoveries

**Data science**
Unlock the power of data

**Visualization**
Pictures paint a thousand words

R&D technology

**Product design and development**
Unlock your potential with data-driven design and development

**Cloud enablement**
Optimize your output on the cloud

**Data engineering**
Mitigate risks, protect your data, and rationalize your portfolio and processes.

Where data means more

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