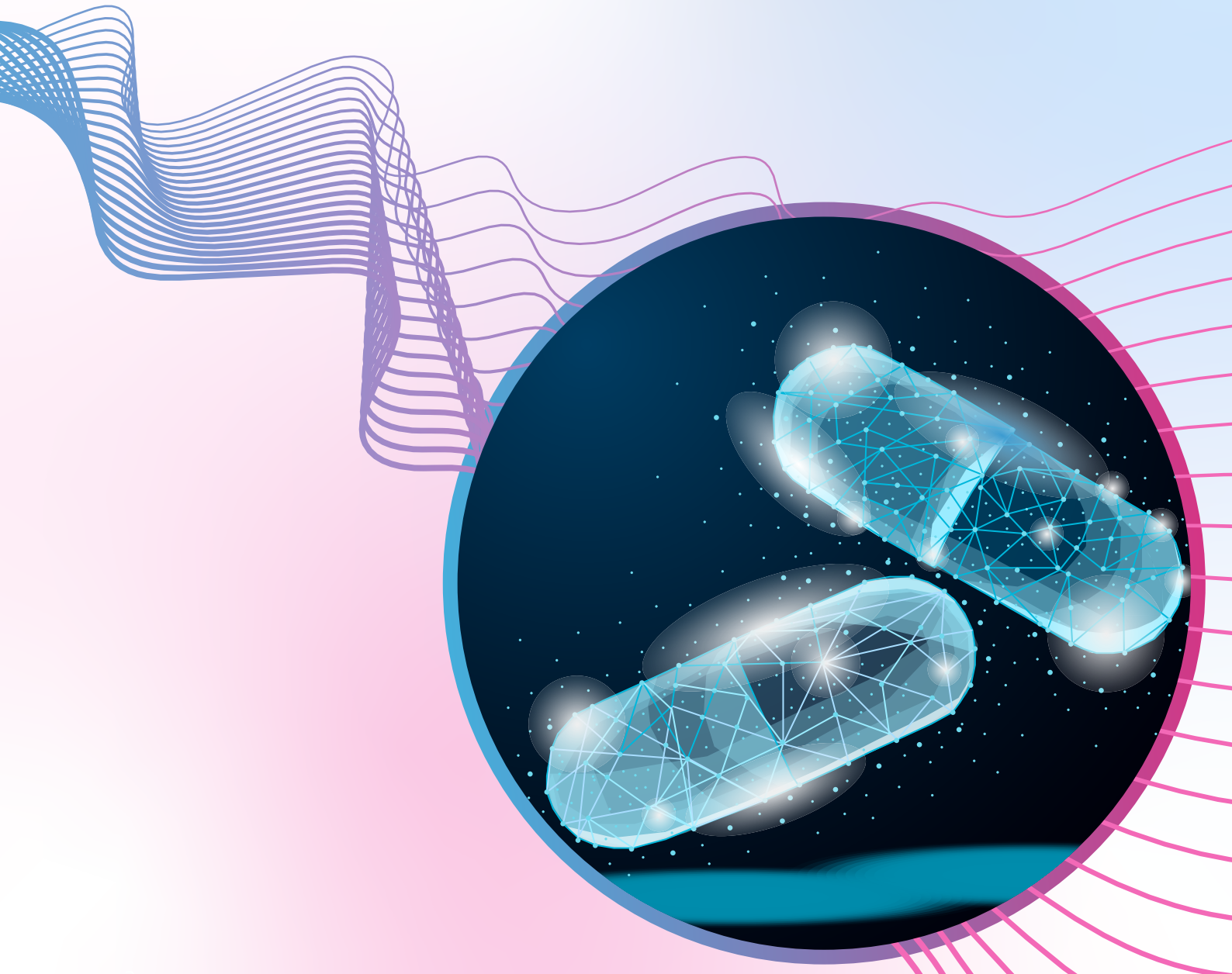
excelra

Case of dose regimen optimization for paclitaxel

CASE STUDY



Purpose

To identify whether optimal paclitaxel dosing regimen for cancer is ‘QW’ (once per week dosing) or 'Q3W' (once every 3 weeks)

Client

Industry
Biotech

Location
US

Sector
Oncology

Requirement

Excelra served a biotech company, which was aiming to quantify a relationship between different paclitaxel doses and regimens on safety and efficacy using summary-level data across published clinical trial literature by model based meta-analysis (MBMA). The aim was to identify and build a database on safety and efficacy data for paclitaxel monotherapy dosing regimens in clinical practice.

Our approach

- Gathered the scope with PICOS methodology for systematic literature search in PubMed.
- Retrieved literature was scientifically screened and labelled with appropriate variables, following which a database was developed to ease further screening and selection of the most appropriate publications as per PICOS specifications.
- After full-text examination, 55 publications describing 49 double-blind phase I, II & III clinical trials with paclitaxel monotherapy in multiple oncology indications were curated.
- A clinical outcome database of these publications was developed by sheer scientific approach to capture clinical outcomes summary data (time vs. response in terms of safety and efficacy endpoints) with all other scoped information for each data point, about patient population (indication), interventions (dose regimen), comparator (dosage regimen), outcomes, study design (sample size) details.
- Process quality was maintained by peer review at each step of database development.

Our contribution

- Excelra provided a refined, structured database i.e. drug-based database for multiple oncology indications (breast cancer, ovarian cancer, glioblastoma, lung cancer, and other mixed tumor types).
- From each study, the data on prespecified essential outcomes that represent safety, efficacy and their associated treatment and dose regimens were extracted using scientific rationale.
- Efficacy end points were captured from tables wherever reported, time to event curves of OS, PFS etc. were digitized for each time point, or censored and recorded in the database.
- The biotech's MBMA on excelra’s data supported the choice of weekly (QW) over every 3-week regimen (Q3W) for the doses included in the modeling, for a better-balanced safety & efficacy profile.

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

excelra

BOSTON | UTRECHT | HYDERABAD

Connect with our experts: marketing@excelra.com

www.excelra.com