Case Study

Case of Dose Regimen Optimization for Paclitaxel

The Purpose

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

About the Client

COMPANY
Biotech

LOCATION
USA

THERAPEUTIC AREA
Oncology

Client 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.

The Excelra 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.

Excelra's 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.

Excelra's Service Portfolio

	Insights	Data
Discovery	• Data Science Driven Drug Discovery • Target Identification • Target Dossier Services	• Chemistry Curation Services • GOSTAR Structure Activity Relationship database
Translational	• Biomarker Discovery • Drug Repositioning • Life Cycle Management • Systems Biology Informatics	• Biology Curation Services • GOBIOM Biomarker intelligence database
Clinical	• Precision Oncology Informatics • Clinical Pharmacology	• Clinical Trial Outcomes Database
Value Evidence	• Outcomes Research • Epidemiology Modelling • Economic Modelling • Value Evidence Communication	• RWE & Big Data Realization • SLR & Meta-analysis
Technology Solutions	• Enterprise Data Strategy • Enterprise Cloud Ops • Enterprise Digital Transformation	

For more information, visit https://www.excelra.com/clinical/#clinical_trial

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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 analyse 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.

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