Case Study

Flexible Design for Novel Trials:

IQVIA IRT supports national lung cancer trial

Background

IQVIA IRT currently provides randomization and trial supply management for the world's largest precision medicine trial to investigate treatment for non-small cell lung cancer. This trial is investigating genetic biomarker targeted therapy combinations, via partnership between non-profit research organizations and large pharmaceutical companies.

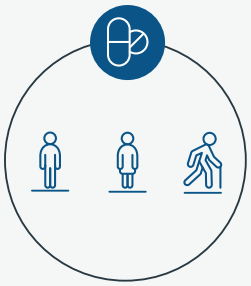
Clinical research program

This umbrella trial is comprised of six distinct mini studies running within, with a seventh arm to be added. Each mini study contains its own dispensing scheme and titration, into which patients have been enrolled for treatment.

As is characteristic of biomarker driven trials, patients in this study have a single disease type that presents a range of genetic changes, which are hypothesized to support cancer cell division and growth. This trial tests a range of therapies by targeting the above mentioned genetic changes in cancer cells. The goal of targeting therapies to cell change is to support doctors in offering patients a precision treatment, one targeted to a specific gene change within their cancer cells.

This trial is running oncology study and treatment cycles ranging from two weeks to a month. During those studies, each patient receives targeted medicine at the beginning of the cycle. This is followed by a second infusion, or additional tablets dispensed to patients. Each treatment in the initial protocol contained down-titration possibilities for varying dosage levels.

Basket clinical trials



Group patients whose cancers contain the same genetic change(regardless of cancer type) and gives them all the same drug that targets this genetic change.

Umbrella clinical trials

Groups patients with the same cancer type, but gives them different drugs, matched to the genetic changes of each of their tumors.

Challenge

Trial design for this type of study presents unique challenges. For example, the IRT platform supporting randomization and trial supply management must support the rapid incorporation of amendments. IRT solution providers must also account for multiple or potential arms which require different lists of material types and dosages that could be prescribed to patients and supplied to sites.

For trial designs of this type, sponsors require the ability to quickly amend the protocol to reflect new or dropped investigational product — all based on patient outcomes. As mentioned earlier, a change of this nature might require a major amendment to the study — requiring new specification and revision phases, and presented as a change order initiated by the sponsor. However, maintaining an accelerated level of activity and forward progress is difficult within a standard Study Change Request (SCR) workflow.

Solution

IQVIA's highly-configurable, flexible technology platform enabled our expert System Design team to design the trial's IRT system for change, from the start. We built the trial with a flexible framework that could easily accommodate anticipated protocol amendments. The team engineered tables within its database to seamlessly accommodate potential new treatments, designed for the known set of existing treatments. We are now in the process of adding the seventh arm to the study.

Based on the nature of precision medicine — the protocol did not, and could not, include all of the specifics. However, IQVIA's team of experts did anticipate the varying types of dispensing, along with other potential variables, based on the 6 treatments. Our System Design team knew that trial patients would receive infusions or tablets throughout various periods, and understood the possibilities of down-titration capabilities for every dispensation.

IQVIA designed the IRT system with placeholders for treatment arms to be added to test the hypothesis if treatment would be effective for each patient. Because IQVIA had created pre-built options, the addition of the seventh arm will not affect the existing visit plans of the initial six treatment arms, saving time for this system update.

Result

IQVIA's IRT platform delivered innovative design, development, validation and deployment of each protocol change — all within the required timeframe while helping keep the trial sponsors in compliance, and patients safe.

A NATIONAL LUNG CANCER TRIAL A BREAKTHROUGH IN PRECISION MEDICINE

STUDY

- The world's largest precision medicine trial to investigate treatments for non-small cell lung cancer

CHALLENGES

- The trial operated as an "umbrella" with 6 mini-trials running within, with a seventh arm to be added
- Patient safety required the IRT system to help sponsors clear major protocol amendments in as little as 2-3 weeks

RESULT

- IQVIA design experts used our flexible, highly adaptable IRT platform to design the trial for change, building in potential treatment arms and anticipating potential changes
- throughout the lifecycle
- IRT solution reflected a blend of standard and customized functionality
- Accelerated delivery and reduced sponsorburden

Orchestrate Outcomes

IQVIA TECHNOLOGIES

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