

# MANAGE COMPLEXITY. EXCEED EXPECTATIONS.

## Clinical Oncology Success: Seamless Drug Development Across Development Phases

A leading pharmaceutical company was developing several molecules for the treatment of a hematologic malignancy. Their two lead compounds were in Phase I first-in-human trials.

The Covance Compound Management Team (CMT) managed the two trials in parallel and then rolled both drugs into a subsequent Phase II non-comparative study. The team accommodated amendments in the ongoing trials to address regulatory agency input on dosage and the need for additional dosing safety cohorts to explore the combination of two novel investigational compounds.

Next, the client initiated two studies to test the safety and efficacy of triplet-combination regimens. Covance supplied a dedicated team, a seamless process and continuous collaboration to shepherd these molecules from early clinical development to the sponsor's late-stage development—with a combination of expertise and efficiency.

### Key Takeways

- ▶ Two molecules had their early-phase trials synchronized to allow for in parallel complex combination late-phase trials
- ▶ Time and cost savings and on time delivery realized through a common Covance management team providing a consistent knowledge base and seamless process
- ▶ Combinations trials involving one or more Immuno-Oncology molecules are becoming common and require exceptional subject matter expertise and special operational consideration to ensure successful development.

### Understanding the Challenges for the CRO

- ▶ **Flexibility and efficiency:** aligning resources and adapting to dynamic study requirements while meeting and/or beating enrollment deadlines
- ▶ **Continuity and communication:** providing one consistent team of experts throughout a complex study to address timelines and ongoing monitor training
- ▶ **Leveraging site relationships:** Investing in long-term investigator site relationships which are leveraged to mitigate difficult situations
- ▶ **Scientific expertise and results:** providing depth of knowledge—from one compound to the complexity of a triplet trial—with all milestones achieved for the client

### A Story of Collaborative Success

These studies involved the entry into human Phase I trials of two novel products for hematologic malignancy. The first molecule was part of a first-in-human trial the sponsor began nine months earlier. The second molecule to enter the first-in-human trial phase was outsourced to Covance. Our team was able to synchronize the timelines for the outsourced trial to match the earlier-starting sponsor-managed trial by implementing a single CMT and managing risks and opportunities across both trials.

Established relationships with key opinion leaders in hematologic malignancies. Helped construct a successful operational strategy. Existing relationships with global Tier One expert sites shortened startup time and ensured therapeutic proficiency.

Establishment of a collaborative relationship among the sponsor medical monitor, the Covance medical monitor, project management teams and the monitoring team helped ensure that the study team and the monitors were well trained on the therapeutic landscape, response criteria plus identifying and reporting expected or unanticipated toxicities directly to the sponsor from the field.

Early in the trial, the Covance medical monitor coached site monitors to effectively identify and manage key side effects—peripheral sensory neuropathy and neutropenia. Because of the teams proficiency, data cleaning was achieved in near-real-time, ensuring that all milestones and safety decisions were achieved on or ahead of schedule. Covance Xcellerate® Informatics modeling tracked both molecules through Phase I and the resulting recommended dosage for the combined Phase II trial.

Moving into Phase II was a seamless and easy transition, with key team members having been in place and working on the Phase II development plan for nearly nine months.

Working as a single Compound Development Team from Day 1, we were able to achieve the client's primary goal: a double-barrel effort to propel both molecules through their life cycles with no disruption or lost time as the molecules moved from the client's early-phase to late-phase organizations.

As the compounds moved between the client's internal development organizations, the same Covance team provided a seamless knowledge base and process—without compromising deliverables, stakeholders or timelines. This continuity avoided expensive delays and learning curves while supporting strategic decision-making by the sponsor.

## The Bottom Line

This complex program revealed the true value of an in-depth collaboration. Proven people and streamlined processes delivered results, meriting high client satisfaction. Long-term relationships and ongoing training proved their worth, with data metrics delivered in near real-time throughout the process plus excellent site communication and engagement.

The sponsor gained consistent, quality data for each consecutive level of decision-making in developing these molecules and making life-cycle investment decisions. Running study phases concurrently sped the process, saving time and money in this highly competitive market.

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## Results

- ▶ Final Phase II protocol was delivered within 8 weeks of the RP2D
- ▶ IRB approval of the Phase II protocol was achieved 4 weeks later and the first patient was dosed within another 4 weeks (~16 weeks after the RP2D)
- ▶ Phase II enrollment consistently trended approximately 35% ahead of the scheduled plan
- ▶ Two Phase II triplet-combination studies launched based on positive interim data cuts from the Phase II study

## Testimonial

I have worked in this industry for 17 years and have worked with many, many CROs, but I have enjoyed working with this Covance team above any others!

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