COVID-19 Case Study: **Delivering Unprecedented Turnaround Time to Enable a Phase I Study**

Understanding the Challenge

A Biotherapeutics company was looking to partner with a CRO to help develop their antiviral compound to treat COVID-19 patients. To align with the urgency of the global pandemic, the client required an accelerated startup and selected Covance to support their expedited drug development needs.

Delivering Expedited Access

Covance started work immediately upon receiving the client's verbal award and assigned a COVID-19 Response Team, a dedicated group that serves as a single point of contact to remove barriers and enable a pan-enterprise collaboration within scientific, medical and operational leadership. The COVID-19 Response Team quickly transferred information and pricing for the program so that the client could initiate funding submission with the Biomedical Advanced Research and Development Authority (BARDA).

Within 24 hours of verbal award, the Covance team created a prioritization plan to enable rapid decisions. Covance leveraged its Infectious Disease team to enable immediate client discussions regarding study design while the Covance Molecule Development Team mapped out the Phase I kickoff plan.

Coordinating Simultaneous Solutions

On the regulatory side, Covance was in contact with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) on a daily basis, fielding questions and facilitating a response to the MHRA within 24 hours after receiving questions. With this information, a Phase I first-in-human protocol was authored, finalized and submitted to the Ethics Committee for review and approval.

To proactively plan for subject recruitment in the first in human study, the client relied on Covance's Phase I capabilities to enable risk mitigation around potential COVID-19 geographical shifts. Meanwhile, another Covance team helped prepare the client's drug supply with the manufacturer.

Within the next three days, Covance authored the investigational medical product dossier (IMPD) and then submitted it to the MHRA.

COVANCE®

Supporting Rapid Responses and Getting to First-in-Human in just 14 business days

Day 1	Day 2	Day 3	Day 4	Day 5
▸ Verbal award ▸ Client discussions ▸ Information transfer ▸ Program costing	▸ Phase I kickoff with Covance Molecular Development Team	▸ Protocol authored & submitted to Ethics Committee	▸ IMPD submitted to MHRA	▸ First Subject Dosed

The Results: Achieving Accelerated Study Startup

The first subject dose was achieved just 8 business days after submission to the MHRA, and 14 business days from the verbal award, highlighting the incredible speed at which Covance and the client operated to ensure that they had a clear path forward to start their urgent clinical program.

For more information on our vaccines and drug development solutions, visit here.

Learn more about our drug development solutions at **www.covance.com**

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