Case study

Central lab service

Enable Successful Phase 1 Clinical Trial for miRNA Cardiovascular and Metabolic Therapy by Chinese Biotech Company

Background

A Chinese biotech company was looking to conduct a Phase 1 trial for a miRNA product focused on cardiovascular and metabolic therapies in Australia. This project required PPD™ Laboratory Services' Central Lab rigorous testing methods and efficient logistics management to meet the challenging timeline.

Challenge

- Validation of the APOCIII methodology to achieve a lower reportable range (0.24 - 160.00 mg/dL) suitable for the specific patient population.
- Aggressive lab data transfer scheme.
- Tight timelines for global sample import into China and sample analysis.
- Delays in method approval due to validation complexities.

Solutions

- Multiple teams collaborated seamlessly to meet the validation completion timelines.
- Team members of the sponsor were regularly informed of method validation updates by the project team. Maintaining regular and close communication with the sponsor.
- Leveraged the global logistic team's professional expertise and effective vendor collaboration to develop efficient international logistics solutions to manage the import of samples.
- Streamlined processes for rapid sample analysis, ensuring timely data availability.

Result

- Successful established testing methodologies fully compliant with CAP/CLIA requirements.
- Our Central Labs strictly adhered to CAP/CLIA/ISO 15189 for assay method validation and clinical sample processing and analysis. Our comprehensive quality control and standard procedures, along with the expertise of our team, ensure the accuracy and reliability of assay results, supporting clinical decisions and research.
- Reduced the preparation time for the data transfer, providing results for dose escalation.
- Comprehensive logistics solutions ensured seamless lab supplies and sample transportation. Exceptional international logistics and collaboration capabilities facilitated the import of samples to China.
- Prompt sample analysis accelerated the clinical trial progression, meeting the project's tight timelines and contributing to overall project success.

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