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aaps PharmSci 360

# Overcoming Challenges: ctDNA Liquid Biopsies in Early Phase Clinical Trials

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LABCONNECT®

# Session Description and Objectives

Define what ctDNA liquid biopsies are and the relevance of this testing to early phase clinical trials

Explore the challenges in testing presented by sample stability, transport logistics, and regional assay readiness, and how they are compounded in global studies

Understand how an FSP model addresses these challenges in domestic and global ctDNA liquid biopsy testing to enhance early phase clinical trials

# Biography and Contact Information

16 years of biomarker experience in preclinical, clinical, commercial product development

Scientific project manager with LabConnect FSP solutions since 2020, managing the outsourcing of biomarker testing for sponsor preclinical and clinical studies

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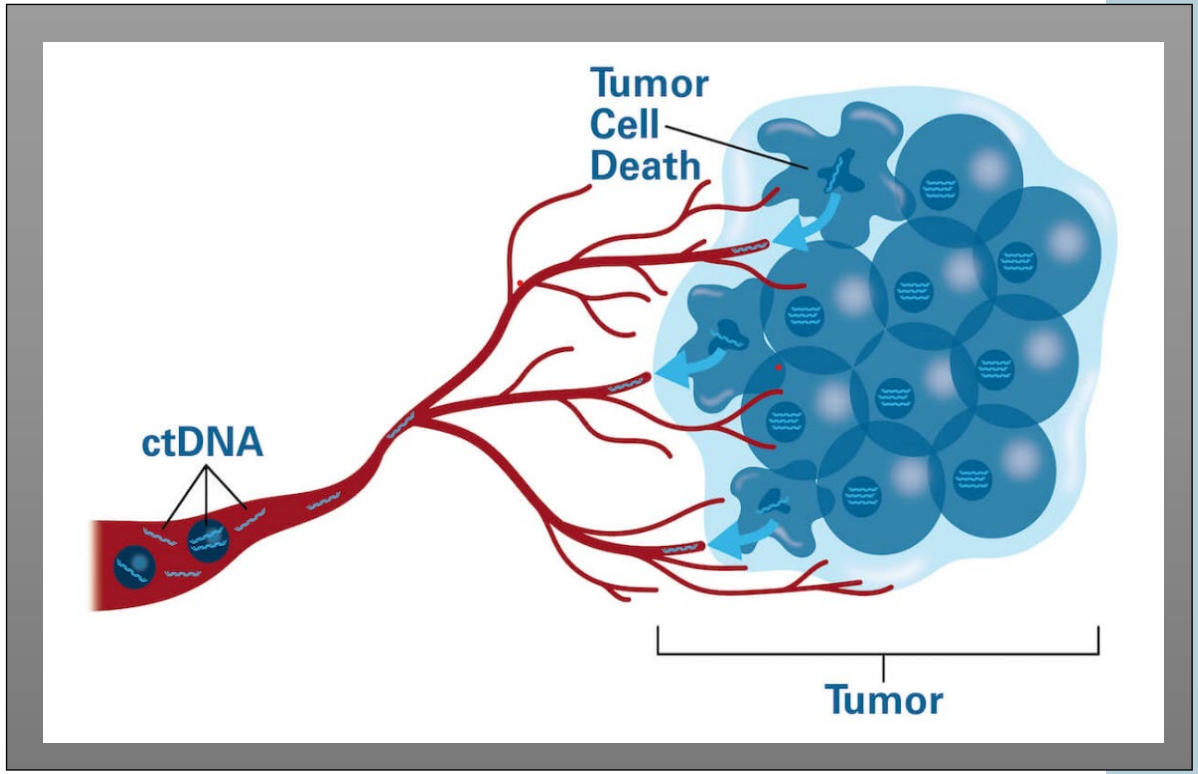
# What are circulating tumor DNA (ctDNA) liquid biopsies and why is the testing relevant to early phase clinical trials

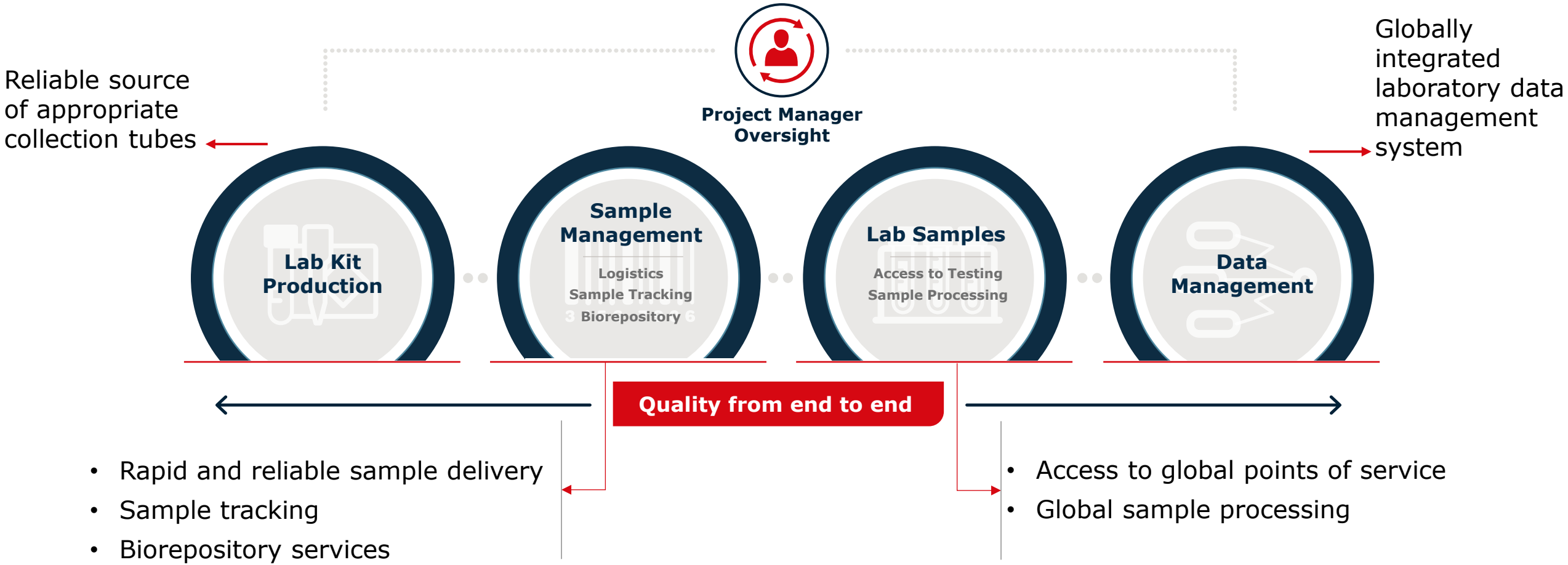



- As a cancerous tumor grows, cells die and are replaced. These dead cells release DNA into the bloodstream and are referred to as ctDNA
- Blood is collected from the patient, ctDNA is isolated from plasma and is genotyped.
  - Can guide in targeted treatment options
  - Monitor patient response to therapy
  - Predictive tool for recurrence of disease
  - Molecular response can precede response seen in RECIST 1.1, allowing subjects to potentially stay on clinical study for a longer duration.

# Sample stability, transport logistics, and regional assay readiness

- Timely isolation, transport, and storage of ctDNA is crucial sample and data integrity
  - Cell lysis begins within a few hours after blood collection, releasing genomic DNA and compromising the sample. ctDNA can be isolated and stored at collection sites, central labs, and sometimes at the specialty lab vendor
- Samples require specialized collection tubes to stabilize the DNA.
  - Limited availability of these collection tubes on the market, and they can be difficult to source to scale for clinical trials
- Availability of testing outside of the United States is limited, therefore sample stability, transport logistics, availability of partner specialty labs, and an international central lab and FSP solutions partner play an important role to the success of liquid biopsy testing

# Key central lab considerations in executing liquid biopsy sample collection, transport, processing, and data delivery



# How can an FSP model address these challenges in domestic and global ctDNA liquid biopsy testing to enhance early phase clinical trials



## Seamless end-to-end integration between Central Lab and FSP

- FSP Solutions Biomarker and Biospecimen project management serve as an extension of the sponsor team
  - FSP Solutions Biomarker project managers liaise on specialty lab vendor selection, study setup, assay development/qualification/validation, and assay maintenance
  - FSP Solutions Biospecimen project managers liaise between sponsor, central lab, and FSP biomarker project manager to ensure sample logistics, sample/data discrepancies, which ensures that sponsor driven timelines are maintained

# Summary

- ctDNA shed from cancerous tumors can be used to guide in targeted treatment options, monitor patient response, predict recurrence, and demonstrate drug response prior to RECIST 1.1
- Sample stability, transport, and regional assay readiness are key to the successful analysis of ctDNA liquid biopsies
  - Short window for sample stability necessitates the use of specific collection tubes to stabilize DNA. These collection tubes have limited market availability and can be difficult to source for large scale clinical trials
  - Limited global availability of liquid biopsy lab vendors adds to the complexity of sample of stability and transport

A full service international central lab can alleviate these issues by providing seamless end to end service with FSP Solutions biospecimen and biomarker project managers, who manage sample/data logistics and technical aspects of liquid biopsy testing.

# Thank You!