

## **Maintaining Specimen Compliance for a High Volume of Complex Clinical Trials**

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### **1. Background**

One of the biggest challenges in managing clinical trials' central laboratory specimens is the increasing complexity of the specimen requirements on individual trials. The higher complexity requires additional effort and oversight to determine and execute specimen needs at each patient appointment. In addition, the reference materials for the specimen management components frequently contain contradictory or unclear information, which requires additional time and specific knowledge to obtain clarification. Lastly, the format of the information provided by sponsor and central labs is not standardized, so it requires additional time to become familiar with the provided information.

### **2. Goals**

- Develop a system that compiles and centralizes the specimen information coming from the protocol, lab manuals, clarification letters, and other reference materials into one uniform source
- Reduce time and effort required to prepare, process, and ship central lab specimens
- Reduce the number of specimen deviations
- Utilize staff skills and knowledge by defining specific roles and responsibilities

### **3. Solutions and Methods**

- Created specimen guides and processing instruction to house the required information to schedule, collect, process, and ship central lab specimens
- Defined roles within the specimen team: junior level staff who complete the day-to-day laboratory operations such as preparing, collecting, processing, and shipping specimens, and senior staff who focus on trial specific information and interpreting protocols and lab manuals

### **4. Outcomes**

We have implemented a system where senior laboratory staff create the documents (specimen guides, processing instructions, and tissue guides) that house the information from all the reference materials and sponsor clarifications in one location and in a single format. These documents are created during trial start-up and updated with each trial amendment. Once these documents obtain dual review and sign-off, they are a single source for the lab operations staff to use during preparing, collecting, processing, and shipping specimens.

### **5. Lessons Learned**

- The process of creating the documents with centralized information is time consuming but the time is recuperated in day-to-day operational steps

Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Completed Project

- Having clear instructions for staff to follow has significantly reduced the number of protocol deviations
- The lab staff now have opportunities for advancement due to the different roles within the team; moving forward, we are shifting the information from Word and Excel documents into a lab information system which links to our clinical trials office patient management database

Figure:

Example of Specimen Guide

Trial Name - Single-Agent Therapy Dose ESC  
 Lab Manual(s): [Exelixis v3.0, Sep2020], [Covance v3.0.0, 19Feb2020]  
 Protocol(s): Protocol(s): Amd 3, 25Jun2020  
 Dual Sign Off Initials & Date: AH 10SEP2020 / AL 25Jan2021

Time Point/Sample Name	Additional Consent	BMP	Sample Cutoff	Shipping	Shipping Temp	Late Adds Acceptable	Collection Day Restrictions	Shipping Restrictions	Window	Kit Name	Kit Provider
<b>Screening</b>											
Archival Tissue (See Tissue Guide)											
Fresh Tissue (See Tissue Guide)											
<b>W1D1 (Day 1)</b>											
SM/Biomarker Plasma			N/A	Primary - Quarterly Back-up - After Primary	Frozen	Yes	No	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
Neutrophil Monocytes, T8NK, & T cell Activity Panel 4			4:00pm	Same Day	Ambient	Yes	M-F only	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
MDSC Assay			4:00pm	Same Day	Ambient	Yes	M-F only	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
CD127, PD1, PS, TREG, TH1, TH2, TH17 T-Cell Assay			4:00pm	Same Day	Ambient	Yes	M-F only	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
PSX Whole Blood DNA (if unable to collect @ W1D1, collect at any visit)			4:00pm	Same Day	Frozen	Yes	M-F only	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
SM/Cell Plasma 1 (CTC whole blood) (urothelial, prostate and NSCLC pts)			4:00pm	Same Day	Ambient	Yes	M-F only	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
SM/Cell Plasma 2 (ctDNA)			N/A	Primary - Monthly Back-up - After Primary	Frozen	Yes	No	M-F only	Pre-dose	ESC Week 1 Day 1	Covance
SM/PK Plasma (Pre-dose AM)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	w/in 30min of dose	ESC Week 1 Day 1	Covance
SM/PK Plasma (1hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 5min	ESC Week 1 Day 1	Covance
SM/PK Plasma (2hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 5min	ESC Week 1 Day 1	Covance
SM/PK Plasma (3hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 15min	ESC Week 1 Day 1	Covance
SM/PK Plasma (4hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 15min	ESC Week 1 Day 1	Covance
SM/PK Plasma (6hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 15min	ESC Week 1 Day 1	Covance
SM/PK Plasma (8hr Post SOI)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 15min	ESC Week 1 Day 1	Covance
SM/PK Plasma (1hr Post PM dose, bid only)			N/A	Primary - @ W1D2 Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 5min	ESC Week 1 Day 1	Covance
<b>W1D2 (Day 2)</b>											
SM/PK Plasma (24hr Post SOI)			3:15pm	Primary - Same Day Back-up - After Primary	Frozen	Yes	No	M-F only	+/- 2,4hrs	ESC Week 1 Day 2	Covance

Example of Processing Instructions

Lab Manual(s): [Exelixis v3.0, Sep2020], [Covance v3.0.0, 19Feb2020]  
 Protocol(s): Amd 3, 25Jun2020  
 Dual Sign Off Initials & Date: AH 02OCT2020 / AL 25Jan2021

Sample Name	Collection Tube	Sensitivity	Processing Instructions	Shipping/Storage Instructions	Shipping Notification	Special Instructions	Protocol Sample Name
SM/Biomarker Plasma	1 x 2mL K2EDTA	Collect on wet ice Process w/in 30min Additional Consent @ progression	-1000g x 30mins @ 4°C Plasma: 5mL tube, mix Equally - 2 x 1.8mL cryovials	Store @ -80°C until shipped Frozen/Quarterly (Primary) After Primary (Back-up) Covance/UPS/M-F	N/A	N/A	Blood Plasma Biomarker
Neutrophil Monocytes, T8NK, & T cell activity Panel 4	1 x 5mL Cyto Chex	Additional Consent @ progression	No Processing	Store @ RT until shipped Ambient/Same Day Covance/UPS/M-F	N/A	N/A	Blood Immune Cell Profile
MDSC Assay	1 x 5mL Cyto Chex	Additional Consent @ progression	No Processing	Store @ RT until shipped Ambient/Same Day Covance/UPS/M-F	N/A	N/A	Blood Immune Cell Profile