Specimen Process

Registration Process:
- Patient must be registered as a study patient in Tolven and have a Subject ID.
- CRC completes Registration CRF.
- Specimen ID are based off of the Subject ID (see below for details).

Tissue Collection [focusing on Stratification Assays]:
- CRC completes Tissue Specimen CRF; this generates the Specimen ID for each tissue sample in Tolven.
- Specimen ID and date of collection are sent from Tolven to caTissue.
- CRC physically sends cores to I-SPY Lab at UCSF.
- If sub-sampling occurs, this is recorded in caTissue and ID extension is added to those sub-sampled samples.
- I-SPY Lab labels sub-sample with Specimen ID and sends it to Agendia [this is to accommodate the auto-population of Specimen IDs in the MammaPrint CRF in Tolven].
  [All other samples are labeled with sub-sample ID and sent to Investigator Labs for analysis]
- Agendia runs sample through assay and reports results in MammaPrint CRF in Tolven.
  [Agendia only at start of trial, all other labs will report results directly to caIntegrator]
- CRC completes CRFs needed by MDACC Randomization Service.
  [ER/PR/HER2 as yes or no, MammaPrint as High 1 or High 2, MRI volume for patient being randomized as well as all MRI volume data to date on all patients at all time points, and all previous patients ER/PR/HER2 MammaPrint & treatment assignment]
- Process is repeated for Early Taxol and Surgery samples (all samples are sent to I-SPY Lab at UCSF).

Blood Collection:
- Blood Specimen CRF is completed by CRC; this generates the Specimen ID for each blood sample in Tolven.
- Specimen ID and data of collection are sent from Tolven to caTissue.
- CRC physically sends samples to I-SPY Lab at UCSF.
- If sub-sampling occurs, this is recorded in caTissue and ID extension is added to those sub-sampled samples.
- Lab runs sample through assay and results are made available in caIntegrator.

Patient ID_	# for Timepoint_	# for type of sample and # for number of samples_	Subsample/ Aliquot # and # quantity_	# for type of Assay
(5 digit #)	(1 digit)	(2 digits)	(either 1, 2, or 3 digits)	(1 digit)
	0- pre-tx	1#- Tissue Frozen	1- H&E stain	1- Affy array
	1- early tx 1	2#- Tissue FFPE	2#- Slide Section (eg. 21, 22, 23 for 3 slides)	2- Agilent array
	2- pre-tx 2/ Inter-regimen	3#- RNAretain	3- DNA	3- MIP array
	3- pre-surgery/ surgery	4#- Serum	4- RNA	4- RPMA
		5#- Plasma	5- miRNA	5- IHC
		6#- Buffy Coat	6- TBD	etc
			91- Aliquot 1	
			92- Aliquot 2…	
			910- Aliquot 10	