Establishment of a Biorepository Network to Facilitate and Advance Translational Cancer Research

CATHOLIC HEALTH INITIATIVES®

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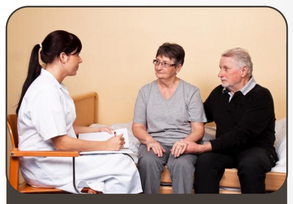
ABSTRACT

Recent advances in genomic and proteomic technologies are fueling the growth of translational research. However, one major factor limiting the advancement of translational research is the lack of clinically annotated biospecimens collected under standardized conditions. To address this unmet need, the Center for Translational Research (CTR) has established state-of-the-art biorepository facilities to collect high quality, clinically annotated and molecularly characterized biospecimens.

By interacting with Physicians, Pathologists, Clinical Researchers and IT team members across the Catholic Health Initiatives (CHI) network (73 community hospitals), the CTR has developed operational, quality and regulatory procedures to standardize hospital workflows, collect and store biospecimens including matched normal tissue and their associated medical data. To maintain quality and provide meaningful biospecimens to advance and facilitate translational research, the CTR collects comprehensive data on pre-sampling, post sampling and logistical variables along with a defined set of clinical data elements for controlled vocabulary, ontology and semantic modeling. In addition, the CTR has developed a robust quality management strategy to govern biorepository operations. These include well defined procedures to manage documents and personnel training (proficiency and competency) records, equipment qualification and validations, freezer temperature monitoring and mapping, CAPA, deviation and change control systems and robust audit programs to ensure the compliance of research operations with all applicable regulations.

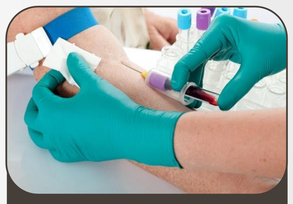
To integrate and manage both operational and quality data, the CTR has partnered with BioFortis to develop a flexible security framework that meets evolving scientific needs and data exchange standards to interface with hospital electronic health record systems. Through its visual search engine, researchers can access integrated clinical, molecular and proteomic data sets and perform intuitive and holistic data mining/analysis to associate genotype with clinical phenotype, thus, translating the biomarker and medical data into useful tests to improve patient outcomes and drive innovation.



Clinical Research Associate discusses Biorepository Protocol and receives written informed consent from patient

Chain of Custody

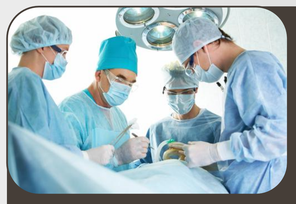
- Date/Time Stamp of Patient Consent
- De-Identified Patient Record Created
- Upload Digitized Copy of Signed Informed Consent Form



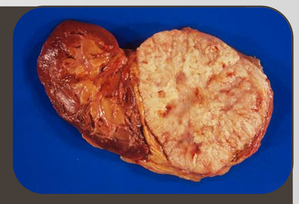
Phlebotomist collects blood samples from consented patient pre-operatively

Chain of Custody

- Date/Time Stamp of Blood Draw
- Type and Number of Blood Tubes Collected
- Date/Time Stamp of Arrival and Storage of Blood Tubes



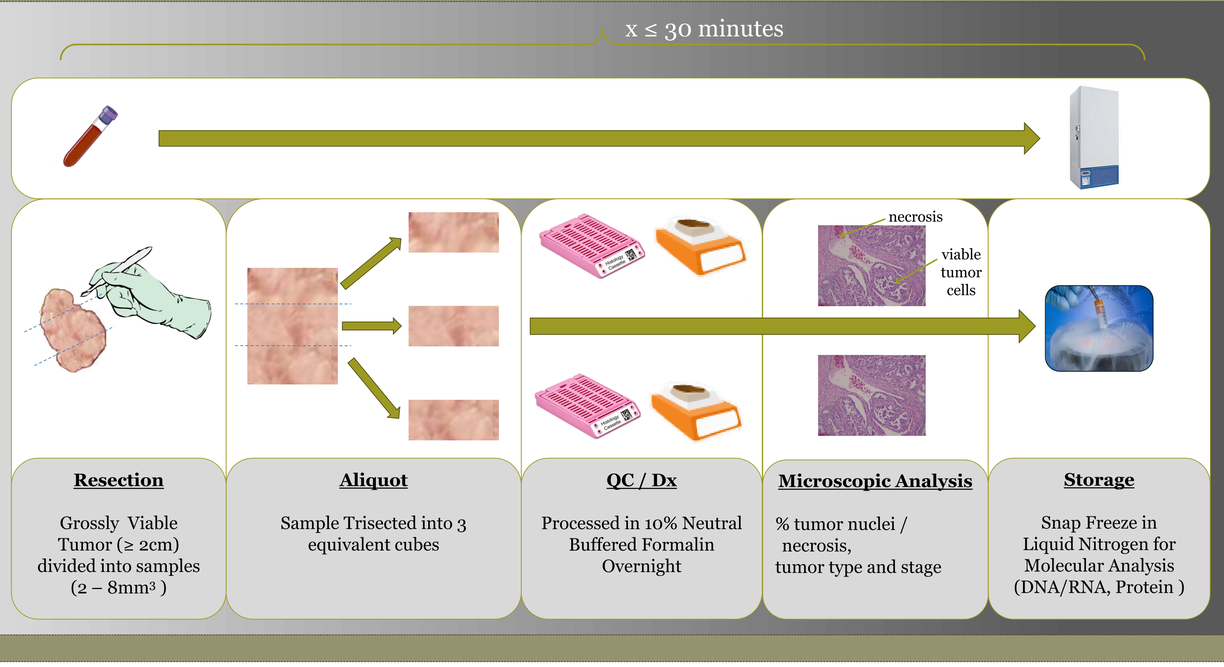
Patient undergoes surgical resection. Fresh specimen transported from OR.

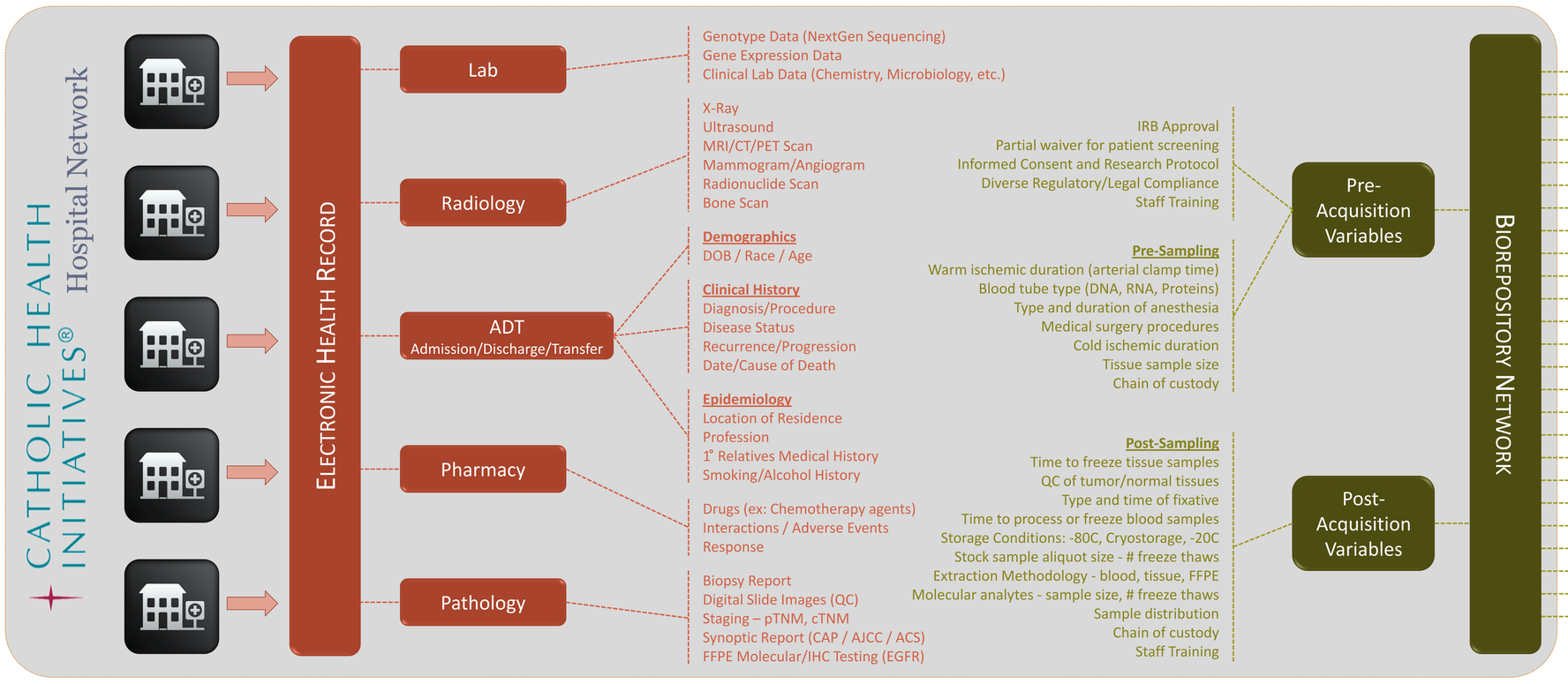


Specimen is macro-dissected by a Pathologists' Assistant under supervision by a Pathologist for collection of tissue

Chain of Custody

- Surgical procedure
- Cold ischemic time
- Date and time of arrival into Lab
- Anatomical gross features of tumor and overall specimen
- Type of storage used
- Date and time each sample is placed into appropriate storage type





CONCLUSION

The success of our biorepository collection across the CHI network of community based hospitals is largely dependent on the development and implementation of standard operating procedures (SOPs) to standardize the collection of biospecimens and associated patient data. These efforts include defining quality control (QC) and chain-of-custody (COC) metrics, developing regulatory and security guidelines to address ethical/privacy requirements, as well as the collaboration and engagement of all staff involved to support a high quality network of biospecimens.

We continue to expand upon the current informatics-guided biospecimen collection program by collecting subjects' standardized clinical data from multiple electronic health record (EHR) systems to build a central repository of richly annotated biospecimens. Utilizing this operational framework model to integrate genomic and clinical data, the CTR focuses on developing infrastructure to create Virtual Patient Cohorts, leading to the advancement of personalized medicine. Access to these integrated data-rich samples will enable the discovery of genotype-phenotype association, thereby assisting clinicians to translate biomarker and patient health data into useful diagnostic tests improving patient outcomes, driving innovation and transforming the healthcare industry.