

# NCI Clinical Trials Network (NCTN) Biospecimen Banks

*Irina A. Lubensky, M.D.*

*Chief, Pathology Investigation & Resources Branch*

*Cancer Diagnosis Program*

*Division of Cancer Treatment & Diagnosis, NCI*

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# NCTN Biospecimen Banks

- Banks are an integral part of the NCTN (supported by U24 grants)
- Unique resource: collect, store and provide researchers with well-annotated specimens and clinical data from NCTN phase III and large phase II trials (adult and children with solid tumors and hematological malignancies)
- NCI Cooperative Group Banking RFA (Cancer Diagnosis Program):
  - U24 Cooperative Agreement Grants/Supplements (9/2005-3/31/2015)
  - Supplements for common IT Navigator development (2012-present)
- New RFA-CA-14-501 (2015-2020) supports a harmonized NCTN banking network (5 Biospecimen Banks) for reorganized 4 Adult and 1 Pediatric NCTN Groups:  
**ALLIANCE, NRG, ECOG-ACRIN, SWOG, COG**

# NCTN Biospecimens

- Biospecimens are associated with detailed clinical data related to therapy, therapeutic response, and clinical outcome.
- Biospecimens are collected by NCTN Groups and affiliated institutions, including National Community Oncology Research Program (NCORP) using special collection kits and SOPs provided by the banks.
- Biospecimens are sent to the NCTN Bank of the Group conducting the trial (lead NCTN Group).
- Participants may consent to the use of their biospecimens for additional studies beyond specific trial objectives.

# NCTN Biospecimens

- Biospecimens are collected on NCTN protocols (U10 grants) and used for integral and integrated biomarker studies/assays (prognosis/prediction).
- Biospecimens that remain in excess after clinical trial requirements have been met become “**legacy**” specimens and are distributed to investigators following a defined NCTN access process and approval of the study by expert review.
- Use of NCTN Biospecimens:
  - Higher priority: Validation studies of predictive/prognostic biomarkers
  - Lower priority: Assay development/validation

# NCTN Biospecimen Banks

- Each NCTN Group is associated with a biospecimen bank.
- Types of biospecimens include:

Frozen tissue	FFPE tissue	Tumor tissue
Non-malign. tissue	Peripheral blood	Bone marrow
Serum / Plasma	Urine	Other biofluids
RNA and DNA	Tissue microarrays	
- Biospecimen organ sites and types are trial dependent.

# Scientific Impact (2008-2013)

- High-dose daunorubicin selectively benefits AML patients with mutations in DNMT3A, NPM1 or MLL translocations (Patel JP, *et al.*, *NEJM*; 2012)
- *OncotypeDx*<sup>TM</sup> test improved risk stratification in stage II & III colon cancer (O'Connell MJ, *et al.*, *J Clin Oncol*; 2010)
- Relative paucity of recurrent somatic mutations in pediatric neuroblastomas challenges current therapeutic strategies that rely on frequently altered oncogenic drivers (Pugh TJ, *et al.*, *Nature Genet*, 2013)
- HPV associated oropharyngeal cancers are a different clinical entity compared to smoking related head and neck cancers (Ang KK, *et al.*, *NEJM*, 2010; & Fakhry C, *et al.*, *JNCI*, 2008)
- Identification of new recurrent mutations, such as ID3, in Burkitt's & DLBCL opens possibility of better clinical trial design in patients with targetable mutations (Love C, *et al.*, *Nature Genet.*, 2012)

# New U24 Banking RFA - Goals

- Support NCTN banking operations/infrastructure
- Consolidate into NCTN biospecimen banking network
- ALL solid tumor & leukemia banking infrastructure & operations with common SOPs
- One U24 banking grant for each new NCTN Group (5 awards)
- Grant PIs – Pathologists, specialists in biospecimen banking
- **NCTN Biospecimen IT Navigator:** common inventory; specimen-data link; search engine for researchers
- **Centralized Front Door process:** access to “legacy” specimens; application tracking, timekeeping
- **One bank for early trials:** CTEP Experimental Therapeutics-Clinical Trials Network ECTN trials

# NCTN IT- Navigator Goals

1. Consolidate  
inventory of  
biospecimens

2. Connect  
biospecimens  
and clinical data

3. Provide  
biospecimen  
access to research  
community

The screenshot shows the NCTN Navigator website interface. At the top, the National Cancer Institute logo and name are displayed, along with the text 'at the National Institutes of Health | www.cancer.gov'. The main content area features a search bar with '653,979 Specimens' and a 'View Results' button. Below the search bar, there are filters for 'Next Element: Intervention Type' and a 'Query' section with 'Expand All' and 'Close All' buttons. The search results show 'Adenoma - Villous' under the 'Primary Diagnosis' category, with 'Match Criteria' set to 'ANY'. A video player overlay is visible in the center, showing a play button and a progress bar at 0:15 / 0:39. On the right side, there is a login section with 'Username' and 'Password' fields, a 'Log in' button, and links for 'Can't Access Navigator?' and 'Guest Access'. Below the search results, there is a section titled 'SCIENTIFIC IMPACT Clinical Trial Biospecimen Utilization' with three articles: 'MicroRNA expression in cytogenetically normal acute myeloid leukemia' (New England Journal of Medicine), 'Improved survival of patients with human papillomavirus-positive head...' (Journal of the National Cancer Institute), and 'The genetic basis of early T-cell precursor acute lymphoblastic leukemia' (Nature). At the bottom, a large banner displays '3,209,756 Total Publications Using NCTN Biospecimens' as of November 5th, 2013.

NATIONAL CANCER INSTITUTE National Cancer Institute at the National Institutes of Health | www.cancer.gov

653,979 Specimens View Results

Next Element: Intervention Type Query Expand All Close All

Trials

Primary Diagnosis

Match Criteria ANY ALL

Adenoma - Villous

Intervention Type

Study Design

Arm

0:15 / 0:39

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**SCIENTIFIC IMPACT** *Clinical Trial Biospecimen Utilization*

MicroRNA expression in cytogenetically normal acute myeloid leukemia  
*New England Journal of Medicine*

Improved survival of patients with human papillomavirus-positive head...  
*Journal of the National Cancer Institute*

The genetic basis of early T-cell precursor acute lymphoblastic leukemia  
*Nature*

Increased EGFR gene copy number detected by FISH predicts outcome in...  
*Journal of Clinical Oncology*

**3,209,756** Total Publications Using NCTN Biospecimens  
*As of November 5th, 2013*

# How To Request Specimens?

- An investigator does not need to be associated with an NCTN Group to request biospecimens.
- The web-based *Biospecimen IT Navigator* will allow investigators to independently query for NCTN Bank biospecimens that meet their criteria, and track their request through the review and approval process.
- The NCTN *Front Door Service* will guide investigators through biospecimen query, application, and regulatory filing procedures.
- The NCTN *Front Door Service* and *Biospecimen IT Navigator* will improve the efficiency and transparency of the biospecimen request process for the entire cancer research community.

# NCTN "Legacy" Biospecimen Request Process

