Biospecimen Banks to Support NCI Clinical Trials

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Biospecimen Banks to Support NCI Clinical Trials

Goal: Collect, process, store and distribute well-annotated NCI Clinical Trials biospecimens for research

- Current NCI support: NCI National Clinical Trials Network Banks (NCTN Banks) & a pilot for the Experimental Therapeutics Clinical Trials Network Bank (ETCTN Bank)

- Future plan is to support: NCTN Banks, expansion of the Early Clinical Trials Bank, and inclusion of the Pediatric Early Phase Clinical Trial Network (PEP-CTN) and NCI Community Oncology Research Program (NCORP) Banking

Grant PIs: Pathologists specialized in biospecimen banking

Governance: NCTN Group Banking Steering Committee (GBC)

Subcommittees:
- Best Practices and Operations
- Access and Marketing
- Informatics
- Regulatory

- Common documents, standard operating procedures (SOPs), Central Manual of Operation (MOO), templates; implementation by all banks
NCTN Biospecimen Banks

- Specimens collected on NCTN phase III, phase II and other trials (protocols); well-annotated with clinical and outcome data

- Specimens initially used by Trial Group Investigators for integral and integrated biomarker studies/assays (prognosis/prediction)

- Specimens remaining in excess after clinical trial requirements have been met become “legacy” specimens and are available to investigators for secondary correlative studies following an NCTN biospecimen access process and approval by NCTN Core Correlative Science Committee (NCTN CCSC)

- Use of NCTN “Legacy” Biospecimens: Validation studies of predictive/prognostic biomarkers based on the trial treatments and outcomes; assay development/validation
<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Samples* Distributed</td>
<td>440,114</td>
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<tr>
<td>- Solid Tumor Samples</td>
<td>410,248</td>
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<tr>
<td>- Leukemia Samples</td>
<td>29,866</td>
</tr>
<tr>
<td>NCTN Investigators Served (Integral/Integrated)</td>
<td>223</td>
</tr>
<tr>
<td>ALL Investigators Served (Legacy Specimens)</td>
<td>348</td>
</tr>
<tr>
<td>- NCTN Group Investigators</td>
<td>220</td>
</tr>
<tr>
<td>- Non-Group Investigators</td>
<td>128</td>
</tr>
<tr>
<td>Publications (based on specimens used for research)</td>
<td>572</td>
</tr>
</tbody>
</table>

*Sample” is defined as one processed piece of a biospecimen, regardless of the sample size or type of initial processing: FFPE block/frozen tissue/vial/aliquot.
### Solid Tumors Samples DISTRIBUTED by NCTN Banks (2013-2017)

<table>
<thead>
<tr>
<th>5 NCTN Groups</th>
<th>Samples</th>
<th>FFPE</th>
<th>Frozen</th>
<th>Plasma</th>
<th>Serum</th>
<th># of Trials OVER ENTIRE 2013 – 2017 PERIOD</th>
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</thead>
<tbody>
<tr>
<td>2013</td>
<td>106,902</td>
<td>41,025</td>
<td>2,042</td>
<td>27,235</td>
<td>18,682</td>
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<tr>
<td>2014</td>
<td>74,163</td>
<td>24,990</td>
<td>1,526</td>
<td>22,155</td>
<td>14,342</td>
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</tr>
<tr>
<td>2015</td>
<td>50,615</td>
<td>34,018</td>
<td>4,404</td>
<td>5,270</td>
<td>7,411</td>
<td>316</td>
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<tr>
<td>2016</td>
<td>78,353</td>
<td>50,746</td>
<td>11,174</td>
<td>2,564</td>
<td>3,103</td>
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</tr>
<tr>
<td>2017</td>
<td>100,215</td>
<td>70,947</td>
<td>9,543</td>
<td>5,831</td>
<td>5,191</td>
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<tr>
<td>TOTAL</td>
<td>410,248</td>
<td>221,726</td>
<td>28,689</td>
<td>63,055</td>
<td>48,729</td>
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### Leukemia Samples DISTRIBUTED by NCTN Banks (2013-2017)

<table>
<thead>
<tr>
<th>4 NCTN Groups</th>
<th>Samples</th>
<th>Bone Marrow</th>
<th>Blood WBC</th>
<th>DNA</th>
<th>RNA</th>
<th># of Trials OVER ENTIRE 2013 – 2017 PERIOD</th>
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</thead>
<tbody>
<tr>
<td>2013</td>
<td>6,823</td>
<td>2,251</td>
<td>265</td>
<td>1,393</td>
<td>1,233</td>
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<tr>
<td>2014</td>
<td>7,410</td>
<td>2,863</td>
<td>794</td>
<td>996</td>
<td>1,100</td>
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<tr>
<td>2015</td>
<td>6,373</td>
<td>3,614</td>
<td>284</td>
<td>1,037</td>
<td>714</td>
<td>83</td>
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<tr>
<td>2016</td>
<td>4,924</td>
<td>1,279</td>
<td>401</td>
<td>988</td>
<td>558</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>4,336</td>
<td>1,475</td>
<td>612</td>
<td>527</td>
<td>341</td>
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<tr>
<td>TOTAL</td>
<td>29,866</td>
<td>11,482</td>
<td>2356</td>
<td>4,941</td>
<td>3,946</td>
<td></td>
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</tbody>
</table>

"# of Trials Over Entire 2013-2017 Period" - number of unique trials involved across all 5 years, as number of trials with active sample distributions will vary from year to year.
ALL Organ Sites, Types and Preparations

<table>
<thead>
<tr>
<th>ALL NCTN Groups</th>
<th>Samples</th>
<th># of Trials OVER ENTIRE 2013 – 2017 PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>348,208</td>
<td>428</td>
</tr>
<tr>
<td>2014</td>
<td>342,677</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>342,246</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>328,657</td>
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<td>2017</td>
<td>280,779</td>
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</tr>
<tr>
<td>TOTAL</td>
<td>1,642,567</td>
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</table>

“# of Trials Over Entire 2013-2017 Period” - number of unique trials involved across all 5 years, as number of trials with active sample collections will vary from year to year.


NCTN “Legacy” Biospecimens-Access
https://navigator.ctsu.org/navigator

1. Consolidate inventory of biospecimens
2. Connect biospecimens and clinical data
3. Provide biospecimen access to research community
4. Track applications

NCI's National Clinical Trials Network (NCTN) Navigator is a resource for investigators who have typically conducted exploratory correlative analysis and are now seeking specimens to validate their hypotheses. Click the "Explore Specimens" button to the right to explore the inventory.

CTEP-IAM Log-In should only be used when you are ready to submit a LOI. If you have questions, please review the FAQs and if your question is not answered there, contact the Front Door Service for assistance.

Navigator Process Flow

The Navigator inventory is currently limited to select adult treatment trials that were conducted by NCI's NCTN clinical trials Groups, Phase 3 or large biospecimen collection protocols with clinical data, and completed, with the primary outcome reported. For additional information on the process workflow, refer to the Steps for Researchers document.

[Diagram showing process flow]
Published Data Load Status as of January 30, 2019

NCTN Navigator Specimens by Disease Category

- **Brain**: 2%
- **Breast**: 30%
- **GI**: 11%
- **Gynecologic**: 31%
- **Head & Neck**: 3%
- **Hematologic**: 3%
- **Lung**: 7%
- **Prostate/GU**: 12%
- **Other**: 1%

- **Total Specimens**: 750,449
- **Total Patients**: 636,091
- **Total Trials**: 110
How To Request NCTN “Legacy” Biospecimens?

- An investigator does not need to be associated with an NCTN Group to request “legacy” biospecimens

- The web-based NCTN Biospecimen Navigator allows 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 guides investigators through biospecimen query, application, and regulatory filing procedures

- The NCTN Front Door Service and Biospecimen Navigator will improve the efficiency and transparency of the biospecimen request process for the entire cancer research community
Rationale to Support Biospecimen Banks for NCI Clinical Trials

Biospecimen Resource for NCTN & Early Trials
• NCTN trial specimens used in a wide range of validation studies of predictive/prognostic biomarkers and assay development; well-utilized and resulted in high-impact publications
• Early Trial specimens used for early clinical evaluation of innovative cancer therapies

External Review: September, 2018 (consensus)
• High value of resource for the research community (translational & clinical research; impact on medical practice)
• Unique trial specimens with clinical annotations and outcome data; harmonized banking SOPs
• Importance of Biospecimen Navigator, Front Door Service, CCSC: provide transparent access to legacy specimens

There is no alternative to the NCTN Banks
• Commercial or academic biospecimen resources cannot supply similar trial specimens for research with broad range of tumor types and detailed annotations
Biospecimen Banks: U24 Cooperative Agreement (2020-2026)

5 NCTN Biospecimen Banks
- Infrastructure and operations
- NCTN Biospecimen IT Navigator & Front Door Service curation
- “Legacy” specimens retrieval, processing, QA/QC
- Specimens for CIMAC (specialized processing/handling)
- Specialized kits and tubes for collection sites & processing
- Digital whole slide images storage/scanning

Early Clinical Trials Bank Expansion (ETCTN, CITN, & CIMAC)

New PEP-CTN Biospecimen Banking in COG NCTN Bank (*)

NCORP Cancer Control & Prevention Trials Banking at NCTN Banks

(*) Banking for the Pediatric Early Phase Clinical Trial Network (PEP-CTN) in the Children’s Oncology Group (COG) NCTN Bank is responsive to the provision of the STAR Act
Questions/Discussion

• Is the rationale/justification for sustained NCI funding to cover clinical trial banking infrastructure and previously unfunded processes and operations adequate?

• What are the functions that NCTN and Early Trials Banks need to fulfill in the future that require NCI investment?

• Will the current and future strategies for improved biospecimen access through the NCTN Biospecimen Navigator help researchers and increase utilization of NCTN “legacy” specimens?

• What are the best ways to increase awareness of NCTN Biospecimen Banks resource to the research community beyond the strategies the program is utilizing currently?