Data Access Toolkit
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Overview

Expanding the CancerLinQ® Offering
CancerLinQ® is a cutting-edge health IT platform that securely connects and powerfully analyzes real-world cancer care data from many data sources. Guided by ASCO’s expertise and mission to support all cancer physicians—in every community and every setting, CancerLinQ equips oncologists with a vast network of information to improve the quality of patient care and outcomes. CancerLinQ is proud to deliver on its promise of transforming cancer care with a CancerLinQ® platform called CancerLinQ Discovery®. The goal of CancerLinQ Discovery is to allow the oncology community to translate big data from CancerLinQ’s pool of de-identified patient data into practical, real-world insights to drive research that can improve the care of all cancer patients.

A Patient Focused Research Product
CancerLinQ Discovery® is designed to further ASCO’s mission of improving patient outcomes and quality, with the long-term goal of enabling the oncology community to learn from the experiences of millions of patients with cancer to help optimize the care of each patient. CancerLinQ Discovery® offers the broader oncology community access to distinct sets of de-identified patient data with the purpose of investigating specific research questions.

CancerLinQ Discovery® is committed to:

- Integrity of research requests – Researcher’s data requests will be reviewed by the CancerLinQ Discovery® Research & Publications Committee, based on their potential to improve patient care
- Protecting privacy – Researchers only have access to statistically de-identified datasets specifically tailored to address their research questions
- Sharing findings with the public – Insights gleaned from CancerLinQ Discovery® that can improve cancer care will be made available to the broader community

Powerful and Robust Data Sets
Through our rapidly growing community of participating practices, CancerLinQ® is on track to become the largest, most comprehensive source of real-world data in oncology. With practices from across the country that include community practices, academic institutions and major health systems, CancerLinQ is developing a diverse and robust clinical oncology dataset to be made available to researchers. As our CancerLinQ membership grows, so will the volume of data in our system, giving CancerLinQ and ASCO the unique opportunity to transform cancer care through the investigation of real-world patient data.
Data Access Process
The CancerLinQ Discovery® Research & Publications Committee — the body charged with reviewing and approving research requests — is accepting requests for data.

Requests for CancerLinQ Discovery® data may include:
- Custom analytic reports prepared by the CancerLinQ Discovery team.
- Controlled, cloud-based access to curated, aggregated, de-identified data on specific diseases or patient populations.

CancerLinQ Discovery will never include identifiable patient and physician data, and users will only be able to access de-identified, anonymized datasets within the CancerLinQ Discovery platform. Access will be limited to the data needed to answer the approved research question.

How to request access to CancerLinQ Discovery® data.
CancerLinQ Discovery is currently accepting applications for research projects from all non-commercially funded researchers.

The overarching CancerLinQ Discovery data access process.

Submit Request
- Centralized process: data request form, on-line upload and submission
- Initial CancerLinQ Discovery® request screening

High-level Data Sufficiency Review
- CancerLinQ Discovery® data availability & quality check — data fit for purpose
- Initial project data specifications and cost estimates determined

CancerLinQ Discovery® Research & Publications Committee Review
- Full review and consensus decision making process
- Committee may request additional information from data requester

Decision on CancerLinQ Discovery® Request
- Requester notified of decision on submitted data request
- Successful requests move forward to identify contract terms, project cost, and provisions of data
Submit your request
The CancerLinQ Discovery® data access request involves one centralized process. First, complete the CancerLinQ Discovery Data Request Application. The on-line fillable form outlines the specifics of the data request (i.e. goals/aims, research methods, data specifications, etc.). Once completed you will upload the application to complete the submission process.

Once the form is complete and submitted, an initial screening of the application will commence to ensure the application materials are complete and the submitted request aligns with ASCO’s mission.

High-level Data Sufficiency Review
Next, a high-level review of data availability, quality, and sufficiency will be performed. At this stage, general pricing may be provided to the requestor, as well as initial project specifications, prior to moving on to an official review. Cost will depend on a range of factors, including an organization’s status as a subscriber of CancerLinQ®, and the complexity of its research requests. Our goal is to make CancerLinQ Discovery’s insights widely available.

Research & Publications Committee Review
Each CancerLinQ Discovery® Data Request Application will be reviewed by the CancerLinQ Discovery Research & Publications Committee and approved before data access is granted. During this stage, the Research & Publications Committee may request additional materials or clarification from the data requester.

The review committee consists of CancerLinQ’s medical director; practicing oncologists, including those from CancerLinQ-participating practices; health services and outcomes researchers; and patient advocates. The committee roster is available at www.CancerLinQ.org/About.

Decision on CLQ Discovery Data® Request
We anticipate that the time from request submission to notification of the Research & Publication Committee decision will be 6-8 weeks. The primary contact associated with each data request, will be informed of the Committee’s decision. Approved requests will move forward and work with CancerLinQ staff to identify final contracting terms and detailed data specifications for the provisioning of CancerLinQ Discovery data.
CancerLinQ Discovery® Data Dictionary

The information contained within this document enumerates the data elements collected by CancerLinQ®. CancerLinQ has two distinct components: the core platform used by oncology practices that contribute data for quality improvement and clinical care, and CancerLinQ Discovery®, the research grade database now available to the entire cancer community. CancerLinQ Discovery allows users to conduct research and analyses on de-identified, fit-for-purpose datasets. All research requests must be approved in advance by the CancerLinQ Discovery Research & Publications Committee.

The Discovery Data Dictionary identifies data elements across three distinct categories.

1. CancerLinQ Subscriber Access Only – Clinical Database (identified)
2. CancerLinQ Subscriber Access Only – Analytic Database (de-identified)
3. CancerLinQ Discovery® – Analytic Database (de-identified)

CancerLinQ Discovery datasets are de-identified as to patient, provider, and practice, and users will only be able to access the data within the CancerLinQ Discovery platform. Access will be limited to the data needed to answer the approved research question(s).

Discovery datasets and reports will initially be available for cohorts of patients by cancer type (anatomic designation). As the CancerLinQ® system matures, the volume and robustness of data available for requests will increase. In addition, some data elements are largely available only through curation (i.e., natural language processing-assisted human data abstraction) and at present restricted to non-small cell lung cancer. Please note, custom curated data sets for other tumor types or data sets of interest can be requested on an individual project basis, and if approved will involve increased time and costs associated with the provisioning of these data.
<table>
<thead>
<tr>
<th>Category</th>
<th>Data Element Inventory</th>
<th>Description</th>
<th>Subscriber Access - clinical database (identified)</th>
<th>Subscriber Access - analytical database (de-identified)</th>
<th>Discovery</th>
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<tbody>
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<tr>
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<tr>
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<td>City or town of the patient's current/usual residence</td>
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<tr>
<td></td>
<td>State</td>
<td>State or province of the patient's current/usual residence (per ISO 3166-1 standards)</td>
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<td>Postal Code</td>
<td>Postal (zip) code of the patient's current/usual residence (US locations: either 5 or 9 digit zip code; Canadian locations: 6 digit postal code)</td>
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<td>Gender</td>
<td>Biological sex of the patient</td>
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<td>Race</td>
<td>Primary race of the person; if multiple race categories are recorded, report the first (per US OMB categories)</td>
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<td>Patient prior history of cancer diagnoses (by ICD-10-CM)</td>
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<td>Mobile Phone</td>
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<td>Insurance Status</td>
<td>Type of insurance carried by the patient at their most recent practice visit</td>
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</table>

**NOTE:** The items in the orange-shaded cells are currently available only through curation (i.e., natural language processing-assisted human data abstraction) and at present restricted to non-small cell lung cancer.
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<thead>
<tr>
<th>Category</th>
<th>Data Element Inventory</th>
<th>Description</th>
<th>Subscriber Access - clinical database (identified)</th>
<th>Subscriber Access - analytical database (de-identified)</th>
<th>Discovery</th>
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<tbody>
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<td>Practice Name</td>
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<td>City</td>
<td>City or town of practice location</td>
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<td>State or province of practice location (per ISO 3166-1 standards)</td>
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<td>Postal (zip) code of practice location (US locations: either 5 or 9 digit zip code)</td>
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<td>Date of practice-patient interaction</td>
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<td>CPT (or equivalent) code describing the practice-patient interaction</td>
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<td>Encounter Type Description</td>
<td>Description of the practice-patient interaction</td>
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<td>Diagnosis</td>
<td>Diagnosis Date</td>
<td>Date of disease diagnosis or onset</td>
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<td>Type of diagnosis (primary, secondary)</td>
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<td>Diagnosis code value</td>
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<td>Behavior</td>
<td>CLQ Diagnosis classification (benign, in situ, malignant, secondary malignancy)</td>
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<td>System</td>
<td>CLQ Diagnosis classification (organ system of diagnosis)</td>
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<td></td>
<td>Anatomic Site</td>
<td>CLQ Diagnosis classification (anatomic organ/site of diagnosis)</td>
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<tr>
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<td>Adverse Event Date</td>
<td>Date of clinical presentation of an adverse event (sentinel events: ER visit, hospitalization, discontinuation/change of planned therapy, or patient death)</td>
<td>X X NSCLC</td>
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<td>Adverse Event Code</td>
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<td>Date pathology report was completed/submitted</td>
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<td>Tumor Histology</td>
<td>Tissue histology from the pathologically reviewed specimen (per ICD-O-3)</td>
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<tr>
<td></td>
<td>Tumor Behavior</td>
<td>Tumor behavior used by pathologists to describe the invasive or non-invasive nature of the tumor (per ICD-O-3)</td>
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<td>Tumor Grade/Differentiation</td>
<td>Pathologic description of the degree of differentiation (per ICD-O-3)</td>
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<td></td>
<td>Tumor Size</td>
<td>Greatest reported unidimensional size of the tumor; for multiple foci, the greatest dimension of the largest lesion (cm, mm)</td>
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<td></td>
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</tbody>
</table>

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<th>Subscriber Access - analytical database</th>
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<tbody>
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<td><strong>Staging</strong></td>
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<td>Staging Date</td>
<td>Date physician documented/recorded staging observations</td>
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<tr>
<td>T</td>
<td>AJCC T</td>
<td>X</td>
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<tr>
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<td>AJCC N</td>
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<td>X</td>
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<tr>
<td>M</td>
<td>AJCC M</td>
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<td>X</td>
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<td>Stage Group</td>
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<tr>
<td>Body Weight</td>
<td>Measured patient body weight (result and unit of measure)</td>
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<td>Measured patient body temperature (result and unit of measure)</td>
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<td>Measured patient respiration rate (result and unit of measure)</td>
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<td>Blood Pressure</td>
<td>Measured patient blood pressure - systolic and diastolic (result and unit of measure)</td>
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<td>Oxygen Saturation</td>
<td>Measured patient oxygen saturation (result and unit of measure)</td>
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<td>BMI</td>
<td>Practice calculated patient body mass index</td>
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<td>BSA</td>
<td>Practice calculated patient body surface area</td>
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<td>Tobacco Use Assessment</td>
<td>Patient smoking status and history</td>
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</tbody>
</table>

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<th>Discovery</th>
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<tr>
<td>Laboratory Tests</td>
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<td>Date lab result reported to the practice</td>
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<td>Reporting Laboratory - Tumor Genomic Testing only</td>
<td>Name of the reporting laboratory or institution name (per CLIA Lab ID)</td>
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<td>NSCLC</td>
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<td>Name of lab test, or the Gene Symbol for genetic tests (per LOINC)</td>
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<td>Numeric or clinical interpretation of lab test result</td>
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<td></td>
<td>Test Method - Tumor Genomic Testing only</td>
<td>Testing method utilized to yield the reported result</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Genetic Variant</td>
<td>Common name of observed variant (genomic test) or HGVS code</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Imaging / Radiology Reports</td>
<td>Imaging Report Date</td>
<td>Date imaging report was completed/ submitted</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Imaging Procedure Type</td>
<td>Type of imaging study performed (per CPT)</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Tumor Size</td>
<td>Greatest reported unidimensional size of the tumor; for multiple foci, the greatest dimension of the largest lesion (cm, mm)</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Regional Lymph Nodes</td>
<td>Anatomic location of regional lymph nodes reported as involved with cancer</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Metastatic Sites</td>
<td>Anatomic organs or distant lymph nodes reported as involved with cancer</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Treatment Plans</td>
<td>Treatment Plan Start Date</td>
<td>Start date of planned path of care</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Treatment Plan Regimen</td>
<td>Name of planned anti-neoplastic drug(s) or regimen</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment Plan Intent</td>
<td>Initial treatment of incident diagnosis (curative), or subsequent-line therapy for recurrent or progressive disease (disease or symptom control)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Treatment Plan End Date</td>
<td>End date of planned path of care</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Medications Ordered</td>
<td>Medication Order Start Date</td>
<td>Date order was issued</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Name</td>
<td>Generic, brand, or package name of ordered drug (per RxNorm)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Administration Route</td>
<td>Ordered route of drug administration</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Dosage</td>
<td>Total ordered dose amount</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Dosage Units</td>
<td>Ordered dose units</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Ordered Cycles</td>
<td>Number of planned cycles or treatment events using the ordered drug</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Medication End Date</td>
<td>Last date on which the ordered drug is planned to be administered</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Medications Administered</td>
<td>Medication Administration Start Date/Time</td>
<td>Date/Time drug administration started</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Name</td>
<td>Generic, brand, or package name of administered drug (per RxNorm)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Administration Route</td>
<td>Route of drug administration</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Dosage</td>
<td>Total administered dose amount</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Drug Dosage Units</td>
<td>Administered dose units</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Medication Administration End Date/Time</td>
<td>Date/Time drug administration event ended</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**NOTE:** The items in the orange-shaded cells are currently available only through curation (i.e., natural language processing-assisted human data abstraction) and at present restricted to non-small cell lung cancer.
<table>
<thead>
<tr>
<th>Category</th>
<th>Data Element Inventory</th>
<th>Description</th>
<th>Subscriber Access - clinical database (identified)</th>
<th>Subscriber Access - analytical database (de-identified)</th>
<th>Discovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Therapy</td>
<td>Radiation Treatment Start Date</td>
<td>Date course of radiation treatment started</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Radiation Treatment Anatomic Site</td>
<td>Anatomic structure or treatment volume of the radiation therapy</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Radiation Treatment Technique</td>
<td>Treatment technique used to deliver/guide the radiation therapy</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Regional Modality</td>
<td>Modality (type of equipment) employed to deliver regional treatments</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Regional Dose</td>
<td>Total regional dose administered to the patient</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Regional Dose Units</td>
<td>Radiation dose units</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Regional Fractions</td>
<td>Total number of fractions (sessions) administered to the patient</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Surgery</td>
<td>Procedure Date</td>
<td>Date the procedure was performed</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Procedure Code</td>
<td>The principle operative procedure (per CPT)</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Discharge Date</td>
<td>Date patient was discharged from the setting where the procedure was performed</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Date of Tumor Response Assessment</td>
<td>Date physician documented characterization of cancer status</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Tumor Response to Therapy</td>
<td>Tumor response to therapy: absent, partial, complete</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Tumor Recurrence or Progression</td>
<td>Evidence of disease recurrence (reappearance after a disease free period) or progression (worsening of tumor burden)</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>Date of Death</td>
<td>Date of patient death</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Cancer Burden at Death</td>
<td>Presence or absence of cancer (any type) at patient death</td>
<td>X</td>
<td>X</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Clinical Trial Enrollment</td>
<td>Patient Clinical Trial Registration Date</td>
<td>Date patient was enrolled or registered in the clinical trial</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Clinical Trial ID</td>
<td>Unique identifier assigned to the clinical trial by the sponsor</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Trial Cohort</td>
<td>The condition or exposure which describes the group or cohort of patients studied in the clinical trial</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Trial Sponsor</td>
<td>Name of the sponsor of the clinical trial (cooperative group name, drug or device company name)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Lab Test Name

<table>
<thead>
<tr>
<th>Complete Blood Count</th>
<th>WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, RDW, Platelet Count, MPV and Differentials: Absolute and Percent - Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive Metabolic Panel</td>
<td>Albumin, Albumin/Globulin Ratio (calculated), Alkaline Phosphatase, ALT, AST, BUN/Creatinine Ratio (calculated), Calcium, Carbon Dioxide, Chloride, Creatinine with GFR Estimated, Globulin (calculated), Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Urea Nitrogen</td>
</tr>
<tr>
<td>Additional Labs</td>
<td>ER, PR, HER2, Gleason Score, Prostate Specific Antigen, Carcinoembryonic Antigen, Glomerular Filtration Rate, Mean Platelet Volume, Creatinine Clearance, Prothrombin Time, Lactate Dehydrogenase, Magnesium, Vitamin B12, O2 Saturation</td>
</tr>
</tbody>
</table>

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Data Request Form
Data Request Form

CancerLinQ Discovery Data Request Form

Instructions: Please complete the form in its entirety. For each question, enter the request information in the corresponding boxes and limit your responses to the word limits noted in each section. Click in the boxes and then type in the information, and/or copy and paste the appropriate information from another document. Some questions require you to select the most appropriate choice in response to a question.

Prior to submitting your request, please review the contents of this form to make sure it includes all of the information you entered in its entirety. If you are unable to include enough information to adequately describe your request in the space provided, you can submit supporting documentation later on this form.

Thank you!

CANCERLINQ DISCOVERY RESEARCH REQUEST:

CONTACT

Name

__________________________________

Title

__________________________________

Organization

__________________________________

Phone Number

__________________________________

Email

__________________________________

Are you a current CancerLinQ subscribing practice?

○ Yes
○ No

Are you an ASCO member?

○ Yes
○ No
Are you a current Conquer Cancer Foundation grantee?

☐ Yes
☐ No

Is this work being done as part of student research?

☐ Yes
☐ No

ASCO/CANCERLINQ CONTACT (if applicable)

Name
__________________________________

Email
__________________________________

PROPOSAL DETAILS

ASCO Data and/or Research Services Requested

☐ Data request (e.g. Discovery data set)
☐ Collaborate in research project (co-PI, consultant or subcontractor)
☐ Provide analytic services (e.g. descriptive analytic report)
☐ Other

What is the "Other" data research services are being requested?
__________________________________

Project Title
__________________________________

Duration of Proposed Project
Start Date: _______________________

Duration of Proposed Project
End Date: _______________________

Summary of project goal(s) & aims(s):
Describe the state of the science, any relevant previous studies, and your justification for the analysis (500 words or less).

Secondary project goal(s), objective(s) if applicable:
Describe project benefits and public interest value (200 words or less):

Summary of research design, proposed analytic methods, and tools (1000 words or less):

---

**RESEARCH TEAM**

Principal Investigator - Name __________________________________
Principal Investigator - Title __________________________________
Principal Investigator - Organization __________________________________
Principal Investigator - Email __________________________________
Is the Principal Investigator an ASCO member?
☐ Yes
☐ No
Principal Investigator - Upload Biosketch

Do you have a Co-Principal Investigator?
☐ Yes
☐ No
Co-Principal Investigator - Name __________________________________
Co-Principal Investigator - Title __________________________________
Co-Principal Investigator - Organization __________________________________
Co-Principal Investigator - Email __________________________________
Is the Co-Principal Investigator an ASCO member?
☐ Yes
☐ No
Co-Principal Investigator - Upload Biosketch
Do you have senior or key personnel to include?

- Yes
- No

Senior/Key Personnel - Name

Senior/Key Personnel - Title

Senior/Key Personnel - Email

Is this person an ASCO member?

- Yes
- No

Do you have other personnel to mention?

- Yes
- No

Other Personnel - Name

Other Personnel - Title

Other Personnel - Email

Is this person an ASCO member?

- Yes
- No

Do you have a statistician who will oversee the analysis?

- Yes
- No

Statistician - Name

Statistician - Title/Designation

Statistician - Organization

Statistician - Email

---

**REQUESTED DATA**

Describe specific data necessary to complete this request - please refer to Discovery Data Access Toolkit for review of potentially available data:

Patient cohort requested - inclusion & exclusion criteria:
Does the proposed research involve hypothesis testing?

- Yes
- No

If yes, please provide sample size and power calculations:

Data cohort Start Date: ______________________

Data cohort End Date: ______________________

Notes or other requirements:

Please upload any additional supporting materials here:

---

**ADDITIONAL PROPOSAL DETAILS**

Dissemination Plan (How will this data be shared with the general cancer community? E.g. Manuscript submission, scholarly presentation, etc.)

IRB Status

- Exempt
- Submitted & Approved
- Under Review
- To be Submitted
- Other

Please provide a copy of your IRB submission and approval (if available).

Comments about "Other" IRB status

---

**PROJECT FUNDING DETAILS**

ASCO charges a fee for services. The fee is dependent on ASCO's determination of level of effort to complete your request.

Does your project have funding?

- Yes
- No
Is the funding source a commercial entity?

☐ Yes
☐ No

Funding Source (List organization information) ________________________________

Funding Agency Contact Name ________________________________

Is this project being proposed for part of a grant application?

☐ Yes
☐ No

Proposal deadline ________________________________
(ASCO does not guarantee we can meet your deadline, but will attempt to respond in a timely manner)

Please attach a copy of the program announcement

Program announcement title ________________________________

Program number (if applicable) ________________________________

TERMS AND CERTIFICATION

CancerLinQ Discovery strives to provide a timely response to requests for data access or reports. As specified in the Data Access Policy, not all data access or report requests may be approved. CancerLinQ Discovery will provide notification regarding a decision or approval or rejection of requests.


☐ Yes
☐ No

I understand that, if my request is approved, I will be required to sign a De-identified Data Use Agreement, a copy of which can be found at www.cancerlinq.org. I certify that I have reviewed this document and I am prepared to sign if my request is approved.

☐ Yes
☐ No
Frequently Asked Questions
Frequently Asked Questions

ASCO’s CancerLinQ® harnesses big data to rapidly improve the quality of care for people with cancer by connecting and analyzing real-world cancer care data from almost any electronic record source. It is the only big data effort in cancer that is being driven by a non-profit, physician organization.

CancerLinQ Discovery®, one of two major components of CancerLinQ, is a secondary resource available to the entire cancer community. It will allow users to conduct research and analyses on curated sets of de-identified data with the objective of creating new clinical knowledge and improving outcomes for patients.

What research will CancerLinQ Discovery® make possible?
CancerLinQ Discovery will power an array of clinical and outcomes research that can lead to better care for people with cancer. For example, it may help researchers identify new uses for existing drugs, refine the use of available treatments in specific patient populations, or uncover factors that doctors can use to predict which patients will experience certain side effects of treatment.

What kinds of data and reports are available?
CancerLinQ Discovery provides controlled, cloud-based access to curated, de-identified data on specific diseases and patient populations. Also available are custom analytic reports prepared by the CancerLinQ Discovery team.

CancerLinQ Discovery datasets are derived from the rapidly-growing CancerLinQ database drawn from the more than 100 oncology practices that are participating in CancerLinQ’s core quality improvement and data-sharing platform.

How will CancerLinQ® consider Discovery research requests?
The request must be consistent with ASCO’s mission of improving quality of care, including identification of practice trends or clinical endpoints that relate to that mission. Requests will be evaluated by the CancerLinQ Discovery Research & Publications Committee before data access is granted. The committee consists of CancerLinQ’s medical director; practicing oncologists, including those from CancerLinQ-participating practices; health services and outcomes researchers; and patient advocates. The committee roster is available at www.CancerLinQ.org/About.

Who can submit research requests to CancerLinQ Discovery®?
CancerLinQ Discovery is currently accepting applications for research projects from all non-commercially funded researchers.

When will CancerLinQ Discovery® be ready to receive research requests?
The CancerLinQ Discovery Research & Publications Committee — the body charged with reviewing and approving research requests — is accepting requests for data.
How do prospective users submit research requests to CancerLinQ Discovery®? What is the anticipated turnaround time?

The CancerLinQ Discovery® data access request involves one centralized process. First, complete the CancerLinQ Discovery Data Request Application. The on-line fillable form outlines the specifics of the data request (i.e. goals/aims, research methods, data specifications, etc.). Once completed you will upload the application to complete the submission process.

Once the form is complete and submitted, an initial screening of the application will commence to ensure the application materials are complete and the submitted request aligns with ASCO’s mission.

Each request received is reviewed by the Research & Publications Committee. We anticipate that the time from request submission to notification of approval will be 6-8 weeks.

How does CancerLinQ Discovery® ensure that patients’ identities are truly protected?

CancerLinQ Discovery uses a widely accepted de-identification process to ensure that users cannot identify specific patients, physicians, or medical practices. Under this approach, which is recognized by the U.S. Department of Health and Human Services’ Office for Civil Rights, experts in bioinformatics remove identifying patient data using accepted statistical and scientific principles and methods.

How does CancerLinQ® ensure the responsible and ethical use of data?

CancerLinQ is committed to rigorous policies and procedures that govern how CancerLinQ data will be used and accessed. The CancerLinQ Data Governance Oversight Committee, a voluntary panel consisting of oncologists and others with expertise in implementing clinical data safeguards, has created policies to direct the efforts of all relevant CancerLinQ staff in the handling of data in a manner that preserves patient trust and complies with federal and state guidelines, including requirements of the Health Insurance Portability and Accountability Act (HIPAA). As part of its commitment to transparency, CancerLinQ’s data governance policies are available publicly at [www.CancerLinQ.org](http://www.CancerLinQ.org).

How much will CancerLinQ Discovery® cost?

The cost of a given research request will depend on a range of factors, including an organization’s non-profit or government status; its status as a subscriber of CancerLinQ; and the complexity of the requests. The goal is to make CancerLinQ Discovery’s insights widely available to the oncology community.
Data Access Policy
Data Access Policy

I. Introduction
The American Society of Clinical Oncology (“ASCO”) and ASCO’s wholly owned subsidiary, CancerLinQ LLC (“CLQ”) are committed to conquering cancer through appropriate, secure, and ethical usage of health information entrusted to CancerLinQ®. ASCO believes that the ability to learn from every patient will accelerate progress against cancer and will give patients and physicians more comprehensive information to make decisions about cancer prognosis and treatment.

CancerLinQ Discovery® is a cancer information resource containing clinical and related data that has been statistically de-identified as to patient and provider. CancerLinQ Discovery is derived from CancerLinQ®, CLQ’s learning health system that is designed to help oncology professionals monitor, coordinate, and improve the quality of care they provide to cancer patients. Participating professionals (“Subscribers”) have given CLQ permission to de-identify the registry-type data they share with CancerLinQ. This secondary information, provisioned in CLQ’s secure cloud environment with approved analytic tools, is expected to also have utility in a range of applications, such as updating and developing quality benchmarks and clinical guidelines, research, hypothesis generation, identification of signals, and provision of reports.

CancerLinQ Discovery® offers an active and responsive data access program. Any individual or entity with a legitimate interest in CancerLinQ Discovery data or reports (“Researcher”) may submit a request to CLQ, using the provided Data Access Request Form. Requests will be evaluated by the CancerLinQ Discovery Research and Publications Committee (R&P Committee) in accordance with this Data Access Policy.

II. Glossary of Terms Used

**Authorized User:** Any individual who is a Researcher or a representative of a Researcher who has been provided authorized access to Discovery Data on behalf of a Researcher subject to a Data Access Agreement.

**Data Use Agreement:** A written agreement signed by CLQ and the Researcher that sets out the permitted uses of Discovery Data and other responsibilities of Researchers and Authorized Users. A Data Use Agreement may be part of a larger agreement between a Researcher and CLQ. Where a Limited Data Set is involved, a Data Use Agreement will be a HIPAA-compliant Data Use Agreement.

**De-Identified Data:** Health information: (a) that has been redacted or otherwise revised to exclude all identifiers specified in 45 CFR § 164.514(b)(2) and with respect to which no actual knowledge exists that the information could be used alone or in combination with other information to identify any individual who is a subject of the information; or (b) that an appropriately qualified professional has determined does not constitute Individually Identifiable Health Information in accordance with 45 CFR § 164.514(b)(1).

**Discovery Data:** De-Identified Data, anonymized as to health care providers, that is derived from the CancerLinQ Subscriber registry and made available as a secondary data resource to Researchers via the CancerLinQ Discovery® platform. Discovery Data may refer to a core data repository or subsets of that core that are provisioned by CLQ and
contain data necessary to address a particular Research question or carry out a Researcher’s approved queries.

**Limited Data Set:** Protected health information that excludes the following direct identifiers of the individual, or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images. Disclosure of a limited data set may only be for the purposes of research, public health, or health care operations, and must be accompanied by a fully executed data use agreement. 45 C.F.R. § 164.514(e).

**Publication:** An abstract, manuscript, slide set, poster, filing, or publishable report based on Discovery Data.

**Research:** A systematic investigation designed to develop or contribute to generalizable knowledge, or other study or analysis approved pursuant to this Policy. Research includes development of Research projects or preparation for Research.

**Report:** A document or dashboard that provides information and analyses gleaned from a review or analysis of Discovery Data carried out by a Researcher or by CLQ on a Researcher’s behalf.

### III. General Policies

A. CancerLinQ Discovery® is intended to further ASCO’s charitable purposes of disseminating oncology information, facilitating collaboration among those involved in oncology, and promoting high quality cancer care. This means, among other things, that all uses of Discovery Data should have the effect of enhancing Discovery Data and the CancerLinQ® registry, and the understanding of their potential uses, for the benefit of all.

B. CLQ (including leadership, workforce, advisors, and volunteers) and Authorized Users, will follow ethical guiding principles of stewardship, protection, transparency, and accountability when making decisions regarding CancerLinQ Discovery data.

C. CLQ and Authorized Users will comply with all applicable laws, regulations, and contractual obligations, including but not limited to HIPAA, Subscriber Participation Agreements and Business Associate Agreements, securities laws, and antitrust laws.

D. Discovery Data remain within a CLQ-controlled environment, where they can be accessed in a secure and approved way by Authorized Users. Only Reports, not the underlying data, may be exported by Authorized Users. CLQ does not sell Discovery Data.

E. Authorized Users are not authorized to access any data that is identifiable to an individual patient, provider, or oncology practice. Authorized Users will not attempt to re-identify any patient, provider, or oncology practice via CancerLinQ Discovery data, alone or in combination with other data sources. Analyses resulting in a cohort of fewer than 10 patients, providers, or practices are not permitted.

F. CancerLinQ Discovery® is a non-exclusive resource. CLQ may, at its option, permit multiple unrelated, but similar or identical, requests or analyses by different Researchers.
G. The R&P Committee has responsibility and authority to review Discovery Data access requests, Research requests, and publications resulting from CancerLinQ Discovery Research.

H. Enhancement and enlargement of the data set available for CancerLinQ Discovery is ongoing. However, CancerLinQ Discovery is provided “as is,” and neither CLQ nor ASCO gives any assurance about Discovery Data’s accuracy, completeness, or fitness for purpose. CLQ does not guarantee the availability or quality of data or other resources to support requests or reports to fulfill requests. CancerLinQ® will make reasonable efforts to, but retains sole discretion whether to, fulfill requests for which data are available and of sufficient quality.

I. All learning about Discovery Data is intended to enhance the resources of CancerLinQ and CancerLinQ Discovery. It is anticipated that data curation, data mapping, and other enhancements to Discovery Data, carried out by and on behalf of Researchers and others, will feed back into the broader data sets for the benefit of all.

J. CLQ is committed to transparency about the uses of Discovery Data. This Policy will be made public. CLQ reserves the right to make periodic reports to Subscribers and the public about the kinds of uses of Discovery Data. Researchers and Projects will not be identified in these reports without the Researcher's permission.

K. Except for work done by CLQ, CLQ does not endorse any Research, Report, or Researcher.

IV. Data Access Requests
A. Individuals and entities requesting access to Discovery Data or Reports must submit a Request Form and provide all required information.

B. IRB approval, if necessary, must accompany requests for access to Discovery Data. CLQ reserves the right to require IRB approval for certain requests.

C. CLQ may assess application and review fees, which may vary depending on the scope and nature of the request.

V. Request Approval Criteria
A. The R&P Committee, supported by CLQ staff, will evaluate a request to determine whether:
   i. The project is consistent with ASCO’s mission, the goal of improving quality of care, or identifying practice trends or clinical endpoints;
   ii. CLQ has the capacity to create Discovery Data cohorts as required for the project;
   iii. The Researcher’s analytic team or the CLQ analytic team has the qualifications and resources to conduct the analyses to completion;
   iv. Discovery Data are “fit for purpose” to carry out the requested Research;
   v. Analytic tools and methodologies proposed by Researcher are compatible with CancerLinQ Discovery and this Policy;
   vi. The proposed project is consistent with CLQ’s privacy and security policies; and
   vii. A plan exists for disseminating the results of the Research.
B. CLQ may ask Researchers to supplement the application or may iterate with Researchers during the review process so as to develop a request that is appropriate for approval.

C. Researchers whose requests are denied may seek reconsideration by the R&P Committee, but CLQ reserves the right in its sole discretion to approve or decline any request.

VI. Data Access and Use
A. If a request is approved, the Researcher’s Authorized Users will be granted access to Discovery Data to the extent necessary to carry out the approved Research.

B. Requestors and Authorized Users are legally bound by the terms of the Data Access Agreement, which is required to be signed prior to awarding credentials to Authorized Users.

C. Use must be limited to the original proposal. If anything in the original proposal changes, the Researcher must seek approval for new use.

D. Researchers are specifically prohibited from linking de-identified CancerLinQ® data with any other dataset, public or private.

E. Data recipients may not attempt to re-identify any individual in a CancerLinQ data set.

VII. Publication Review
A. Any Publication resulting from the Research or based on Discovery Data must be reviewed and approved by the R&P Committee before it is submitted to a congress or journal or otherwise released beyond the Researcher.

B. The R&P Committee will review the Publication to assure that it is consistent with the approved project, that it accurately characterizes Discovery Data, that authorship is appropriately acknowledged, and that there is no express or implied CLQ endorsement of an external Researcher’s work or product.

C. A CLQ disclaimer may be required to be included with the Publication.

D. R&P Committee review does not assess or validate research methods or results. R&P Committee review is not a substitute for peer review, which is independently performed by relevant associations, congresses, and journals.

E. R&P Committee approval of a Publication does not assure acceptance of the Publication by any ASCO meeting or journal. ASCO educational programs and publications are independent and peer reviewed, and have sole discretion over the work accepted.
VIII. Miscellaneous Provisions
A. The specific terms of written agreements between Researchers and CLQ may supersede portions of this Policy and the R&P Committee Charter and normal work flow. This includes but is not limited to access timelines, application fees and review timelines.

B. CLQ reserves the right to audit any Research or Report.

C. After a project is concluded, Researcher’s access to Discovery Data will be terminated. CLQ will use reasonable efforts to provide access to a copy of the Research data set to the extent required by a journal, funding source, or regulatory body and if CLQ is given adequate notice of the requirement.

Approved by the CancerLinQ Board of Governors [December 13, 2016] Approved by the ASCO Board Executive Committee [December 14, 2016]
Sample Data Use Agreement
Sample Data Use Agreement

This Agreement ("Agreement") is made as of [DATE of AGREEMENT] by and between [Data Recipient Entity Name] "Data Recipient" and the CancerLinQ LLC ("CLQ"). Data Recipient and/or CLQ may also be referred to individually as "Party" or collectively as "Parties."

WHEREAS, Data Recipient desires to perform certain Research as defined herein; CLQ is willing to furnish Data Recipient with access to certain data and/or data analytics derived from the CancerLinQ Discovery de-identified data repository; and Data Recipient has all necessary permissions to and is willing to receive from CLQ such information;

WHEREAS, the information exchange, data use, research, analysis, transparency, and dissemination contemplated under this Agreement are consistent with the educational, instructional, scholarship, charitable, or research objectives of each of the Parties;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, Data Recipient and CLQ agree as follows:

1 Drafters note – remove before signing. For multi-institution projects, each institution may sign a separate agreement with identical Exhibit As or all institutions may sign a single agreement (with some modifications to the template).
1. This Agreement governs the terms on which Data Recipient is granted access to and limited use of certain statistically de-identified cancer clinical information provisioned by CLQ or its licensee. In signing this Agreement, Data Recipient agrees, on behalf of itself and of all individuals and entities involved in the Research, to be bound by the terms and conditions of access and use set out in this Agreement.

2. Definitions:
   a. “Access Policy” means the CancerLinQ Discovery Data Access Policy as from time to time in effect and promulgated by CLQ.
   b. “Authorized User” means any individual under the control of Data Recipient, who is given permission by Data Recipient to access the Data on behalf of Data Recipient subject to the terms and conditions of this Agreement, provided such individual signs a copy of the Access Terms attached hereto as Exhibit D. For avoidance of doubt, Authorized Users may include investigators, employees, contractors, or students of Data Recipient.
   c. “Commercial Entity” means any (a) for-profit entity, (b) company in the healthcare industry, (c) entity or provider involved in biopharma, medtech, medical device and medical supplies, or financial services, (d) private and public payer, (e) commercial laboratory or contract research organization, or (f) subcontractor, consultant, partner, or agent acting on behalf of any of the foregoing entities; in each case as determined by CLQ in its sole discretion.
   d. “Data” means a defined set of de-identified clinical oncology data or information created or assembled by or on behalf of CLQ for its own purposes, to which access is furnished to Data Recipient by or on behalf of CLQ for the sole purpose of carrying out the Research. Data does not include and shall not contain or constitute “Protected Health Information” (“PHI”) as defined in 45 C.F.R. Section 160.103 and shall not contain CancerLinQ subscriber or health care provider identities.
   e. “Data Recipient” means the entity captioned above that is granted access to and limited use of the Data by and from CLQ.
   f. “Publication” means, any report or work describing, stemming from, or based in whole or in part on, the Research or the Data, including, without limitation, articles published in print or online journals or repositories, electronic journals, reviews, books, abstracts, posters and other written, digital and verbal presentations and representations of Research.
   g. “Research” has the meaning set forth in the Access Policy.

3. CLQ will furnish access to Data to Authorized Users, in a manner and format it deems reasonable and appropriate, consistent with the description in Exhibit B, attached hereto and made a part hereof. Data Recipient agrees that Exhibit B accurately and adequately describes the Data furnished hereunder and fulfills Data Recipient's data request. Data access is limited to the time required to carry out the Research and prepare Publications, subject to the term of this Agreement. Data may be maintained by CLQ beyond the term of this Agreement to the extent it is required to be deposited in connection with a peer reviewed publication or governmental submission. Access may be denied to any Authorized User who has failed to follow the terms of this Agreement, Exhibit D, or the Access Policy.

4. Data Recipient agrees to access and use the Data solely for the Research described in Exhibit A. Data Recipient represents and warrants that all information contained in Exhibit A is true, correct, and complete. Data Recipient agrees and acknowledges that any

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2 Drafter’s note – remove before signing. Each individual who accesses Data must sign Exhibit D. Separate copies of Exhibit D can be used, or the Data Recipient may maintain one Exhibit D with multiple signatures. A signed copy of Exhibit D for each and every Authorized User must be maintained by the institution and provided to CancerLinQ upon request.
follow-on, different, or subsequent use of the Data requires a new application and independent review and approval under CLQ’s then current Access Policy and procedures.

5. Data Recipient will pay to CLQ the amounts set forth in Exhibit C, attached hereto and made a part hereof. If Exhibit C calls for CLQ to provide invoices, Data Recipient will pay each invoice within thirty (30) days of receipt.

6. CLQ expressly retains ownership of, and all rights, title, and interest in, Data, including data sets and all elements of Data, as well as in CLQ analytic reports, feasibility assessments, and records of review under the Access Policy. Data Recipient will own all rights, title and interest in Publications except to the extent that CLQ or a CLQ employee, volunteer, or agent is an author of such a Publication under accepted scientific authorship standards. CLQ will not have ownership or intellectual property rights in discoveries and inventions stemming from Research unless specifically agreed in writing by the Parties.

7. Data Recipient hereby represents and warrants that it is not a Commercial Entity, that the Research is not sponsored or financed by a Commercial Entity, and that no individual involved in the Research, including but not limited to Authorized Users, is involved in the capacity of an employee, consultant, or agent of a Commercial Entity. Data Recipient agrees not to use the Data or any part thereof for or in connection with the creation of products or tools for sale, license, or for any commercial purpose at any time. Data Recipient will not use any discovery or invention directly derived from Data for commercial purposes. Data Recipient will not, and will not permit third parties, to use Data or Research to market to health care providers or consumers.

8. Data Recipient agrees to preserve, at all times, the confidentiality of Data and of any other CLQ information marked as Confidential. Data Recipient shall not copy or remove Data from the secure hosting environment provided by CLQ. Data Recipient shall not use or disclose Data except in carrying out the Research and Publication as permitted in this Agreement and the Access Policy. Without limiting the generality of the foregoing, Data Recipient will not, and will not permit any third party to, make the data widely or publicly accessible. Data Recipient agrees not to attempt to re-identify Data as to any patient or any individual or institutional health care provider. Data Recipient agrees not to link Data with other data sets. Data Recipient agrees not to contact any patient or individual or institutional health care provider based on information derived from the Data. Depositing the data with a journal in connection with scholarly publication may be permitted in CLQ’s discretion with appropriate controls over security and access. Data Recipient will ensure that Authorized Users comply with the terms of this Section 8. Data Recipient will immediately notify CLQ of any known or suspected event or action that is inconsistent with this Section 8.

9. Data Recipient agrees to utilize the Data and to carry out the Research in compliance with all applicable federal, state, and international laws, regulations, and scientific or ethical codes, including, without limitation, health data privacy and security laws, rules for the protection of human research subjects, rules governing drug approval, and policies of applicable journals, congresses, and research institutions. Data Recipient will comply, and will cause all Authorized Users to comply, with the Access Policy. Data Recipient will make reasonable efforts to develop Publication(s) based on the Research. If CLQ, ASCO (including its committees and task forces), or Conquer Cancer (the ASCO Foundation) are directly involved in Data analysis or in funding, overseeing, or carrying out the Research, Publications will first be submitted to one or more ASCO journals or outlets.
10. Data Recipient agrees to accurately acknowledge CancerLinQ Discovery as the source of the Data in any Publication, using acknowledgement language substantially in the form provided by CLQ in connection with Publication review. Such acknowledgement shall in no way imply or suggest endorsement of Data Recipient, the Research, or any health product, therapy, or entity, whether by CLQ, American Society of Clinical Oncology, or any of their respective officers, directors, employees, volunteers, agents, or licensees. Other than such footnote or other acknowledgement, nothing in this Agreement gives Data Recipient any license or right to use any name, logo, or other trademark of CancerLinQ LLC or American Society of Clinical Oncology or any other affiliate thereof.

11. Data Recipient agrees to provide advance review of each Publication as described in the FAccess Policy. Before submitting a Publication to a third party, Data Recipient will remove any information that is confidential and proprietary to CLQ, in the reasonable good faith judgment of CLQ.

12. Data Recipient understands and acknowledges that the Data may be protected by copyright and other intellectual property rights, and that duplication, (except as reasonably required to carry out Data Recipient’s research with the Data), transfer, or sale of all or part of the Data in any media or by any channel is not permitted.

13. The Parties recognize that nothing in this Agreement shall operate to transfer to Data Recipient any intellectual property rights relating to the Data. Data Recipient has the right to develop intellectual property based on comparisons with other data to which Data Recipient has necessary rights. Nothing in this Agreement prevents CLQ from furnishing the same Data to others.

14. This Agreement will be effective upon the date first written above and shall continue in effect for a period of thirty-six (36) months unless a different period is specified in Exhibit B or unless the Agreement is earlier terminated. Either Party may terminate this Agreement at any time upon thirty (30) days’ prior written notice to the other party. Upon termination, Data Recipient shall immediately discontinue use of the Data, and CLQ shall terminate Authorized Users’ access to the Data. Any breach of this Agreement by Data Recipient will result in immediate termination of this Agreement, loss of access to Data, and denial or withdrawal of Publication approval.

15. Data Recipient understands and agrees that CLQ will from time to time disclose high-level descriptions of research projects utilizing CancerLinQ Discovery CLQ data to various audiences, including, without limitation, to members of the American Society of Clinical Oncology, subscribers of the CancerLinQ platform, CLQ’s and its affiliates’ governing bodies and volunteer committees, CLQ licensees, the media, and the public. Data Recipient grants CLQ permission to disclose a general description of the Research, drawn from Exhibit A, to such audiences.

16. All Data are provided strictly “as is.” CLQ is not responsible for, and expressly disclaims any representation, warranty or liability with respect to, the accuracy, completeness, fitness for purpose, timeliness, provenance, or integrity of such Data. CLQ has and shall have no liability for research, clinical, operational, technical, business, or any other decisions made or actions taken, whether by Data Recipient or by any other person or entity, on the basis of the Data. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, CLQ DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR ANY OTHER STATUTORY OR COMMON LAW WARRANTY TO THE EXTENT WAIVABLE BY LAW, WITH RESPECT TO THE DATA, THE ANALYTICS, THE TRADEMARK, OR CLQ’S COURSE OF DEALING.
17. NEITHER CLQ NOR DATA RECIPIENT WILL BE LIABLE FOR INDIRECT, CONSEQUENTIAL, OR INCIDENTAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF PROFITS, REVENUE, DATA, OR USE) ARISING OUT OF THIS AGREEMENT AND/OR ANY DISCLOSURES OF DATA RECEIVED OR CREATED UNDER THIS AGREEMENT, WHETHER IN A LEGAL ACTION IN CONTRACT OR TORT, EVEN IF THE APPLICABLE PARTY IS ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE ENTIRE LIABILITY OF CLQ AND ITS AFFILIATES, DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS UNDER THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT OF FEES AND COSTS PAID BY DATA RECIPIENT HEREUNDER.

18. The terms of this Agreement that, by their sense and context, are intended to survive the termination of this Agreement shall survive the Agreement’s termination, including without limitation Paragraphs 3, 4, 6, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, and 19 and Exhibits A and D.

19. All notices under this Agreement shall be in writing and shall be effective when delivered by hand-delivery, or sent by United States registered or certified mail, postage prepaid and return receipt requested, or consigned to an established overnight mail carrier, and addressed or delivered to the Parties at the following addresses (or such other address as may hereafter be designated by the Parties):

If to CLQ:
CancerLinQ LLC
2318 Mill Road, Suite 800
Alexandria, VA 22314
Attn: Chief Executive Officer

A copy of any notice shall be sent to the attention of the Chief Legal Officer of CLQ at the same address.

If to Data Recipient: [Please include notice address]

20. Data Recipient shall not assign, license, nor transfer Data, nor any interest in this Agreement without the prior written consent of CLQ. This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and permitted assigns.

21. This Agreement, with its attachments, constitutes the entire agreement between the Parties regarding the subject matter hereof and supersedes any other written or oral understanding of the Parties. This Agreement, including but not limited to Exhibit A, may not be modified except by written instrument executed by both Parties and signed by an authorizing authority representing each Party.

22. The Parties agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. This Agreement may be executed separately or independently in any number of counterparts, each and all of which together shall be deemed to have been executed simultaneously and for all purposes to be one Agreement. The Parties further waive any right to challenge the admissibility or authenticity of this Agreement in a court of law based solely on the absence of an original signature.

[Signature page follows]
IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

**CANCERLINQ LLC**

By: _____________________________________________
Print Name: ______________________________________
Title: _____________________________________________
Date: _____________________________________________

**[RESEARCH INSTITUTION NAME]**

By: _____________________________________________
Print Name: ______________________________________
Title: _____________________________________________
Date: _____________________________________________

**READ AND UNDERSTOOD:**

By: _____________________________________________
Print Principal Investigator’s Name: _____________________________
Title: _____________________________________________
Date: _____________________________________________
Exhibit A
Project Application

*Include:*
- Data Request Form submitted by applicant
- All supplementary materials
- Any revisions or conditions resulting from the RPC process
- Identity of principal investigator
- CLQ approved acknowledgement language for Publications if available
Exhibit B
Specification of Data to be Furnished

May include timelines, curation specs, delivery/access method, retention periods etc.
Exhibit C
Access Fees

Add amount to be paid and timing of payment(s).
Exhibit D
Authorized User Access Terms

I, _____________________________, understand that I may be granted access to certain de-identified health data (the “Data”) that was disclosed to [INSERT DATA RECIPIENT NAME] (the “Data Recipient”) for specific research purposes (the “Project”) and pursuant to a CancerLinQ Discovery Data Access and Use Agreement (the “Agreement”). I further understand that Data Recipient is contractually required to ensure that all individuals receiving access to the Data agree in writing to the following Access Terms.

In consideration of my having access to the Data, I understand and agree that:

• I will comply with all applicable privacy, security, and confidentiality policies adopted by, or provided to me by, Data Recipient.
• I will keep my personal access code(s), user ID(s), access keys and password(s) used to access computer systems or other equipment or facilities confidential and secure at all times. This is including but not limited to my personal access code, user ID, access key, or password used to access the Data.
• I will not access or view any Data other than that required to perform my responsibilities in connection with the Project as laid out by Data Recipient.
• I will make no attempt to use the Data either alone or with other information, to identify an individual whose information is included in the Data. I will not permit anyone else to do so or grant access to anyone that I suspect might attempt to do so.
• I will make no attempt to contact, directly or indirectly, any individual whose information is included in the Data. I will not permit anyone else to do so or grant access to anyone that I suspect might attempt to do so.
• I will not make any unauthorized transmissions, copies, disclosures, inquiries, modifications or deletion of the Data. Unauthorized transmissions include, but are not limited to, removing or transferring the Data from the CancerLinQ Discovery computer system or environment to any unauthorized location.
• When my authorized access to the Data ends, I will immediately return to Data Recipient all of its property related to access to the Data, including electronic devices, ID badges, documents, keys, access cards, etc., and will make no effort to retain passwords, etc. needed to access the Data.
• I have no ownership or property interest whatsoever in any Data that I receive, create, access or view.
• I will notify Data Recipient’s privacy officer and/or executive management immediately, and in any case within one business day, if (a) I violate any of these Access Terms, (b) I become aware of a breach or suspected breach of the Agreement or violation of these Access Terms by anyone, or (c) I become aware of an attempt by anyone to re-identify the Data or link the Data with other data sources.
• Any violation of these Access Terms may result in disciplinary action, up to and including the loss of access to the Data, the termination of my association with Data Recipient, a lawsuit against me, or referral to law enforcement authorities.
• My obligations under these Access Terms continue throughout and after the conclusion of my (a) access to the Data, (b) participation in the Research, and (c) association with Data Recipient.
Authorized User

Name _____________________________________________
Title _____________________________________________
Signature __________________________________________
Date ______________________________________________

[INSERT DATA RECIPIENT NAME]

By ______________________________________________
Title _____________________________________________
Signature __________________________________________
Date ______________________________________________