User's Manual

global.stjude.org

Version 2.1

Contents

Introduction

Virtually fatal 50 years ago, pediatric cancer is now curable for the more than 80% of children who have access to contemporary treatments and robust supportive care.[1] Often hailed as a modern medical success story, translating these outcomes to improve care among the more than 90% of children who live in low- and middle-income countries (LMIC) as defined by the World Bank has proven difficult.[2,3] While multiple clinical, policy, and financial obstacles contribute, utilizing epidemiologic data to inform cancer control planning is a requisite first step. Unfortunately, we still do not know with reasonable certainty how many children develop, get diagnosed, are treated, and potentially survive cancer around the world each year.[4,5]

Globally, the real incidence of childhood cancer for different causes, like underdiagnosis, especially in scenarios with poor access to primary care or misdiagnosis related to lack of availability of the standard diagnostic tests and specialized care is underestimated due to 60% of countries lacking quality population-based registries and those with registries covering a fraction of the population.[6]

If the comprehensive estimations reported by Atun *et al.* (2020) are combined with the high-quality outputs from bold pediatric oncology registries, the potential for improvement could be optimized and better targeted and adapted to different settings to accelerate the improvements in quantity and quality of life for children with cancer. This is where the Hospital-based Cancer Registries have the most impact. Measuring, tracking, and continuously improving the quality of care provided at hospitals represents a unique opportunity to make impactful changes to improve patient outcomes in the short, medium, and long term at institutions. Collecting and analyzing hospital-based pediatric oncology, high quality data provides the opportunity to strengthen each hospital as a health system unit as well as collectively at a national, regional, and global level.

To achieve the goal of patient tracking and identification of quality improvement interventions, and to ensure efficient treatment prioritization, pharmaceutical supply, budget forecasting, and a myriad of other planning needs, an accurate appraisal of how many and what types of childhood cancers are being managed at a local hospital is necessary. However, collection of these data in limited resource settings must balance the quantity of information against the limited resources available for accurate collection. To standardize childhood cancer data and data collection at hospitals worldwide (including clinical diagnoses and observed events) and support quality improvement processes moving forward, the St. Jude Department of Global Pediatric Medicine (dGPM) aims to establish a Global Hospital-Based Pediatric Cancer Registry Network built on the St. Jude Clinical Trial Platform with a phenocopy available in REDCap with data standards designed specifically for LMICs and in alignment with population-based registries.

The primary objective of the SJCARES Cancer Registry is to implement and maintain a high-quality data repository for pediatric hospital-based cancer registration in hospitals in limited resource settings. Secondary objectives are to establish a prospective cohort of children and adolescents diagnosed with malignancies and treated at participating St. Jude Global Alliance member institutions, assess the frequency, distribution, and survival of childhood cancers presenting to St. Jude Global Alliance member institutions, identify local barriers to both registry implementation and obtaining high-quality pediatric cancer registry data, and to quantify the administrative costs of implementing and running hospital-based cancer registries.

Fostering and strengthening hospital-based pediatric cancer registries represents a powerful opportunity to improve the quality of care while providing relevant information to strengthen population-based registries with the ultimate goal of increasing quantity and quality of life.

Thank you for being part of this registration effort that allows us to prevent a child with cancer from being invisible and for supporting us in this effort to create a brighter future for children with cancer worldwide.

Sincerely,

The SJCARES Cancer Registry Team

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Section One: Administration of the Registry

1. Overview

This manual is intended for SJCARES Cancer Registry users from institutions and hospital sites that have signed the St. Jude Global Alliance Membership as well as Data Use and Transfer Agreements.

Information contained in this manual relates to SJCARES Cancer Registry operations and procedures to provide clear directives on implementation and collection of high-quality childhood cancer data on a global scale. The Table of Contents lists critical subjects that users can reference when clarification is needed; for example, information about roles and responsibilities, data security, training, and data collection procedures and scenarios are all included in this manual.

2. Registry Organization, Roles and Responsibilities

2.1. St. Jude Registry Advisory Panel

Research studies and projects utilizing the SJCARES Cancer Registry de-identified Data Warehouse will be reviewed by the SJCARES [Cancer] Registry Advisory Panel in addition of the Project Concept Proposal Committee. Investigators wishing to access Registry data for research purposes must submit a scientific concept proposal to the PCP and RAP, with objectives, methodology, and composition of the project team that will be using the data; if approved, the principal investigator will obtain and use the data solely for the purposes and project described and approved.

2.2. Sponsor and Coordinating Center

St. Jude Global will act as both the sponsor and coordinating center for this initiative. As the sponsor, St. Jude Global is responsible for organizing and providing oversight to the Registry in addition to collaborating with local site investigators in registry development and implementation. As the coordinating center, St. Jude Global is responsible for overall data management, monitoring, and communication among all sites, as well as general oversight of registry procedures such as regulatory guidance, site staff training, and quality assurance.

There are two St. Jude-based Global Registry team roles with respect to data management: (1) SJ Registry Data Associate (SJ CRA) who will perform quality assurance on all iCRFs (essential information, demographics, diagnosis, staging, treatment, and follow-up forms); and (2) SJ Trial Manager (SJ Database Administrator) who will have read-only capabilities for data elements and will participate in quality assurance activities as well as registry report generation. Both St. Jude Global Registry team roles are blinded to Protected Health Information (PHI) variables, including names, national and reference IDs, addresses, phone numbers, and email addresses. The SJG Cancer Registry team may be contacted by emailing registry@stjude.org.

For additional information on PHI and de-identification, please refer to page 2 of the sample Data Transfer Agreement available on the Registry website [https://www.stjude.org/global/sjcares/registry.html] under the Data Ownership and Collaboration tab.

2.3. Participating Sites

St. Jude Global Regional teams will prioritize sites that are interested in implementing the Registry as well as work collaboratively with St. Jude Global Operations, the St. Jude Global Cancer Registry team, and specific sites. These collaborating teams will aide sites with completing Alliance

applications, signing all appropriate agreements, confirming reasonable internet access, assessing staffing needs specifically for data entry, selecting site-level registry roles, training, and implementation.

There are two local hospital site-level roles: (1) Data Entry Specialist, also called a data coordinator or data manager, who will be responsible for all pediatric cancer patient data entry; and (2) MD Monitor, who should be a physician, pediatric oncologist, or pediatrician, and who will review (or monitor) entered data for quality. The MD Monitor is responsible for general oversight of the Registry activities at the hospital institution.

Refer to www.stjude.org/sjcares for the SJCARES framework.

Regarding the St. Jude Global Alliance Governance, refer to the St. Jude Global Alliance Membership Agreement and SJCARES Registry Rider, additional documents executed by country site collaborators and St. Jude Global.

3. Glossary

St. Jude Global (SJG): an initiative developed by the Department of Global Pediatric Medicine (dGPM) at St. Jude (SJ) in Memphis, TN to address disparities and improve care and survival related to childhood cancer and catastrophic diseases.

St. Jude Global Alliance (SJGA) Governance: members of SJG Operations, the SJ Executive Committee, and the SJ Department of Global Pediatric Medicine; purpose is to facilitate knowledge and skill sharing among SJGA members and provide guidance and oversight on procedures, agreements, information management, monitoring, and communication

Project Concept Proposal Committee (PCP/C): the PCP is comprised of various multidisciplinary specialists, including Global Pediatric Medicine (GPM) faculty and others who contribute to vet and monitor the overall research projects and/or clinical trials portfolio within GPM.

SJCARES [Cancer] Registry Advisory Panel (RAP): is a collaborative group of individuals representing the Global Alliance Members participating in SJCARES Registry activities across the Regions and St. Jude Global affiliates who serve across the Department of Global Pediatric Medicine to operationalize the Global Alliance Goals. This group convenes to review the research proposals and to provide feedback and guidance as needed.

St. Jude Clinical Research Associate (SJ CRA): a registry team member in the Global Pediatric Medicine Department at St. Jude, responsible for data quality activities.

St. Jude Database Administrator: a Registry team member in the Global Pediatric Medicine Department at St. Jude with read-only capabilities for data elements who will participate in quality assurance activities as well as generating registry reports.

St. Jude Global Cancer Registry Team: the team in SJG working on the Registry; includes the SJ CRA, the SJ Database Administrator, the Program Director, and the statistical analysts.

The Registry: the SJCARES (hospital-based) Cancer Registry, also known as CAREREG.

SJCARES Cancer Registry Platform: refers to the Anju and TrialMaster, unless otherwise specified.

Anju: the Vendor company that owns and hosts TrialMaster [Anju EDC].

TrialMaster [Anju EDC]: the Electronic Data Capture (EDC) application in which the SJCARES Cancer Registry is designed.

iCRF: the electronic data collection document in the SJCARES Cancer Registry Platform. Also called electronic case report form (eCRF), case form, case report form, CRF, electronic form, or Registry form. There are six (6) Registry iCRFs - Essential Information, Demographics, Diagnosis, Staging, Treatment, and Follow-Up.

St. Jude Global Regional Team: collaborators primarily located in Memphis, TN that aid in network development, sharing knowledge, and stakeholder integration in global health, research, and innovation across locations and programs. Examples of St. Jude Global Regions include Sub-Saharan Africa, Eastern Mediterranean, Central and South America, Asia-Pacific, China, Mexico, and Eurasia.

Data Entry Specialist: a data coordinator or data manager responsible for all pediatric cancer patient data entry at the site; this person may have a medical background (MD/RN), however a medical background is not required.

MD Monitor: a physician, pediatric oncologist, or pediatrician who will review entered data for quality and who is responsible for general oversite of the Registry at the hospital site.

Hospital Site Registry Team: individuals at the site using the Registry; this team will include at least one Data Entry Specialist and one MD Monitor.

SJCARES de-identified Data Warehouse: St. Jude Global Childhood Cancer Analytics Resource and Epidemiologic Surveillance System (SJCARES). A secure data warehouse where Member Institutions that use the Data Registry will store and share de-identified data to form a global registry where any authorized representative of a St. Jude Global Alliance Institution Member may access the de-identified data and use for reporting and research, subject to the policies and procedures of the St. Jude Global Alliance and further terms defined in this Agreement.

4. Communications Plan (Notifications)

Changes or updates to the Registry will be communicated via email to hospital site users from the Registry team email, registry@stjude.org. The St. Jude Global Registry team may also send these update messages directly through email as well.

Queries, or quality checks on data entered, can be communicated and assigned by the hospital site MD Monitor as well as the St. Jude Global Registry Team roles. When assigned a query, or Registry data element to address, this will appear in the “My Queries” section of the Reports in the Registry database, the user must respond and address the query in the database as soon as possible (within one week) to ensure data quality consistency.

5. Training

5.1. Site Initiation

In order for a hospital or institutional site to begin operating the SJCARES Cancer Registry the site must have signed Alliance and Data Use/Transfer Agreements, completed the Site Worksheet, and

confirmed reasonable internet access; also, a minimum of two individuals is required to operate and maintain the Registry at each site. These two individuals will fill one of two roles that have specific permissions relating to registry data entry, queries, reports, and quality assurance; the two site roles are the MD Monitor and the Data Entry Specialist.

5.2. MD Monitor training requirements

The MD Monitor will perform general oversight of the Registry and ensure data accuracy and quality at their site. The MD Monitor will monitor the iCRFs, be alerted to check discrepancies in data when flagged by the system, and be able to assign queries when necessary. Each site MD Monitor should at minimum be a licensed physician; note that this individual would be considered the Principle Investigator (PI) if this were a research project. All MD Monitors are encouraged to take the course "Clinical Data Abstraction in Pediatric Oncology" administered by St. Jude Cure4Kids and are required to complete the SJCARES Cancer Registration Course and SJCARES Cancer Registry Platform (TrialMaster) e-learning courses. All training course module assessments must be passed to demonstrate a complete understanding of the material. Upon completion and satisfactory assessment scores, MD Monitors will be provided access to the Registry.

5.3. Data Entry Specialist training requirements

The Data Entry Specialist will perform registry data entry and ensure data recording accuracy at his/her site. Each site Data Entry Specialist should at minimum be familiar with medical terminology. All Registry Data Entry Specialists are required to complete the course "Clinical Data Abstraction in Pediatric Oncology" administered by St. Jude Cure4Kids, the SJCARES Cancer Registration Course, as well as SJCARES Cancer Registry Platform (TrialMaster)e-learning courses. All training course module assessments must be passed to demonstrate a complete understanding of the material. Upon completion and satisfactory assessment scores, Data Entry Specialists will be provided access to the Registry.

5.4. Distribution of training materials

A member of the St. Jude Global Registry team will contact all identified Site Registry Team members regarding Cure4Kids training enrollment via email [from registry@stjude.org]. Training materials will be made available online (https://www.cure4kids.org/); Data Abstraction, SJCARES Cancer Registration, and SJCARES Cancer Registry Platform (TrialMaster) Course documents can all be downloaded through the Cure4Kids platform.

5.5. Training courses

Training tracks and related coursework are as follows:

Course Name	**MD Monitor** (must be a physician/MD)	**Data Entry Specialist** with medical (MD/RN) professional background	**Data Entry Specialist** without medical (MD/RN) background
Data Abstraction Course, Intro to Pediatric Oncology Module	Optional	Optional	Required
Data Abstraction Course, Intro to Clinical Data Abstraction Module	Optional	Required	Required
Cancer Registration Course	Required	Required	Required
SJCARES Cancer Registry Platform Training Tutorial	Required	Required	Required

If an individual does not obtain a satisfactory assessment score and fails to pass a course, the learner must retake and complete the course and corresponding course assessment. Training courses for the Registry are linked: a learner must complete and pass assessments for one course before moving on to the next course. All course certifications will be provided through the Cure4Kids platform upon completion and passing assessments. You do not need to share your certificates because a member of St. Jude Global will also have access to these certifications through Cure4Kids.

6. Case Eligibility

Registry Inclusion: For patients to be included into the Registry, all of the following criteria must be met:

- have a malignant hematologic or oncologic diagnosis inclusive of myelodysplastic syndrome and histiocytic diseases;
- have a date of birth no earlier than January 1, 1980;
- be less than 21 years of age at the time of diagnosis;
  AND
- be either diagnosed or receive some form of treatment (curative or palliative intent) at the institution of registration.

Registry Data Entry: In addition to entering in new patients and patients currently enrolled on therapy at the time of implementing the Registry, we also encourage entering patients who were diagnosed prior to initiation of the Registry. Ideally, as a minimum goal, we recommend sites with the capacity to do so enter patients into the Registry starting 5 years back from the date of implementing the Registry. Care needs to be taken to ensure inclusion of all eligible patients.

Registry Exclusion: Individuals diagnosed with non-malignant hematologic or non-oncologic conditions such as immunodeficiencies or rheumatologic conditions that may require cytotoxic chemotherapeutics or immunotherapy; and/or individuals who do not meet the inclusion criteria discussed above are excluded from the Registry.

- For cases where a patient comes with a non-malignant diagnosis or non-oncologic condition, do not register the patient in the SJCARES Cancer Registry. If the patient is suspected to have cancer and is registered in the system but the diagnostic tests confirm it is NOT a malignant hematologic or oncologic condition, the patient record can be kept in the system and reported as a NON-cancer diagnosis. For patients with NON-cancer diagnoses, the system will not track any staging, treatment, or follow-up.

7. Informed Consent and Confidentiality

The goal of the SJCARES Cancer Registry is to collect epidemiological data about childhood cancer patients in LMICs, including relapse and death, for the purposes of quality improvement and patient tracking. The St. Jude Institutional Review Board has designated the SJCARES registration, surveillance, and reporting tool as non-human subject research, therefore obtaining patient informed consent is not necessary.

The risk associated with registries is unapproved disclosure of identifiable private information/breach of confidentiality; specific to SJCARES this risk may include unapproved access to the database or the

system being “hacked.” The Registry conforms to global regulations for data security and access to the database is controlled by strict account management. Local site MD Monitors and Data Entry Specialists are required to be trained on the appropriate handling of paper-based patient data as well as digital data prior to the provision of SJCARES Cancer Registry access.

A unique SJCARES ID will be created for each registered patient. Only registry staff at local sites will have access to the link to the patients’ medical records (i.e. national and reference identification numbers assigned by each site). Protected health information data entered in the database will not be accessible by anyone not located at the local site. For quality assurance monitoring and data re-abstraction purposes, St. Jude Registry team staff can be provided access to medical records and registry protected health information only during on-site monitoring visits.

In circumstances where local IRB submission and approval is required for implementation of the SJCARES Cancer Registry, the St. Jude Global Registry team can provide a template IRB form identifying the Registry as a patient tracking tool for the purposes of quality improvement, in English, for use by local Registry teams.

8. Data Management

8.1. Data Use Policies

Refer to the Data Use and Transfer Agreement [available on the Registry website https://www.stjude.org/global/sjcares/registry.html].

8.2. Data Security Procedures

The SJCARES Cancer Registry is developed using the **Anju TrialMaster platform (i.e. SJCARES Cancer Registry Platform)**. Anju is an independent, leading eClinical solutions company that supports clinical trials and registry work around the globe. St. Jude contracts with Anju to provide a safe, secure, and compliant eClinical solution for the SJCARES Cancer Registry.

How does the SJCARES Cancer Registry Platform protect site data in the SJCARES Cancer Registry?
SJCARES Cancer Registry Platform performs security monitoring of Registry instances on St. Jude's behalf. If potential security incidents are detected, St. Jude is alerted so action can be taken. **SJCARES Cancer Registry Platform** maintains compliance with 21 CFR Part 11 and makes available to St. Jude attestation reports to its compliance. **SJCARES Cancer Registry Platform** maintains formal disaster recovery plans and procedures. St. Jude has a designated contact whom **SJCARES Cancer Registry Platform** notifies in the event it is triggering disaster recovery failover procedures. Transmissions of data between a St. Jude Global Alliance Member program and the SJCARES Cancer Registry Platform (TrialMaster) service uses HTTPS encrypted communications methods. Regular external audits are performed on their data centers physical and logical security measures and practices. Logs are maintained for any access of records in the Registry. If **SJCARES Cancer Registry Platform’s** service is compromised or if **SJCARES Cancer Registry Platform** informs us of any activity that would indicate that a site’s data has been accessed by an unauthorized party, we will report this information to a site’s coordinator within 72 hours of this notification or discovery as dictated in the terms of the data use agreement.

Are data from my Registry site mixed with data from other studies and/or Alliance Members?

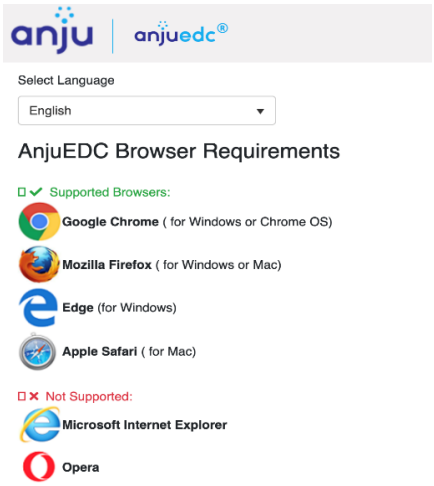
No. St. Jude's trials data is segmented and housed on separate servers and is not co-mingled with other SJCARES Cancer Registry Platform clients. In addition to this server level segmentation, your data is segmented from other sites in the registry by the security and data protection measures designed in TrialMaster.

I see that I will own the data at my center but are my data also being shared with others?
Data use rights are defined in the Data Use Agreement signed by both the sites and St. Jude Children's Research Hospital. We do not share a site's data without their explicit permission and the conditions and requirements for data sharing are detailed in the Data Use Agreement. We do ask for site permission to de-identify data and house the information in a global distributed data warehouse. The academic benefits of participating in this system are spelled out in the Data Use and Transfer Agreement.

How are personal health identifiers managed to ensure compliance with data privacy laws?
Any access by support staff at St. Jude will have personal health identifiers (names, national IDs, reference IDs, address fields) hidden and not viewable by St. Jude staff. Only staff on the Hospital Site Registry Team at the Alliance Member institution for a particular registry instance can view personal health identifiers. For additional information on PHI and de-identification, please refer to page 2 of the sample Data Transfer Agreement available on the Registry website [https://www.stjude.org/global/sjcares/registry.html] under the Data Ownership and Collaboration tab.

How will I log-in to the SJCARES Cancer Registry Platform and is it secure?
Access to the SJCARES Cancer Registry Platform is controlled on a per-registry basis. Each registry uses role-based access controls, with roles designed during registry setup to enforce least privilege. All access to a registry instance within the SJCARES Cancer Registry Platform requires authentication using a valid username and password combination. SJCARES Cancer Registry Platform encrypts all passwords in storage; SJCARES Cancer Registry Platform user accounts are secured via complex password pattern requirements and forced password changes occur at a regular interval.

The SJCARES Cancer Registry is an electronic, hospital-based, online database tool with firewalls to protect patient information and therefore requires internet access at participating hospitals/institutions for optimum utilization. Recommended browsers for TrialMaster version5.1 (Anju EDC v5.1):



Other useful internet browser information:

Component	Description
Operating System (OS)	-Windows 10 -Macintosh OS High Sierra
Browser (latest version)	-Chrome, Firefox, or Edge on Windows -Chrome, Firefox, or Safari on Macintosh
Mobile Device	-iPad

What YOU must do to help keep your SJCARES Cancer Registry data safe:

- Keep your software (operating system and applications) updated. Run supported versions of software that receive periodic updates to address security issues and vulnerabilities.
- Use a screen locking solution to control access to your system when you step away from the computer.
- Run antivirus on your computers and keep this software and its virus definitions up to date.
- Use a firewall solution on the computer.
- Limit non-business use of the system used to access the SJCARES Cancer Registry.
- Limit who has administrative access to systems.
- Be careful when installing applications or browser plug-ins. Install solutions only from trusted sources.
- Do NOT share your log in credentials with anyone.

9. Quality Control Procedures

The utility of the Registry depends entirely on the quality of the data provided by its users. The following procedures are designed to protect the integrity of the Registry and the reports and analyses that are generated from it. Participating sites are expected to comply with these procedures in order to remain in good standing. Registry sites are encouraged to develop local practices that promote a continual state of "monitor readiness" as a part of standard data quality practices and to expedite any request for monitoring that may arise.

9.1. Data Queries

The SJ CRA will routinely review data entered into the Registry for completeness, consistency, and timeliness. Registry site users should routinely review the monthly query reports sent via email from the St. Jude Global Registry Team, which can include various types of queries: TrialMaster data queries, Delinquent forms, Potential Duplicate Patients, and/or Extreme and negative durations. TrialMaster data queries will be entered directly into the SJCARES Cancer Registry Platform system by the SJ CRA. Registry site users are expected to respond to queries within two weeks from the query date. In most cases, source documentation should be reviewed and correction, if deemed appropriate by the Data Entry Specialist and/or MD Monitor, should be made directly in the SJCARES Cancer Registry Platform. Local Registry staff should contact the SJ CRA at registry@stjude.org if additional clarifications are needed.

9.2. Data and Site Monitoring

Due to the broad scope of the SJCARES Cancer Registry and the characteristics of cancer registries in general, routine monitoring of source documentation and in-person site monitoring are neither

feasible nor appropriate. However, limited monitoring of source documentation and/or site monitoring may be deemed appropriate by the Registry Advisory Panel and/or SJG Registry Team in certain situations.

If a Registry site will be monitored and/or a site visit is planned, the SJ CRA will notify the MD Monitor by email, detailing the scope and timing of the data monitoring and/or site visit, and will work with the site to determine a mutually agreeable time frame for the monitoring and/or visit.

For data monitoring, a "data freeze" date will be determined, at which point the SJ CRA will compare primary source documents with the Registry data. The SJ CRA will then notify the Registry site. An itemized list of findings will be presented to the MD Monitor and other local staff within 4 weeks of the monitoring. A description of the requested response and deadlines of response will be detailed at that time.

For a site visit, a summary of site findings will be presented to the Registry team, with an itemized list of findings emailed to the MD Monitor within 2 weeks of the visit. A description of the requested response and deadline of response will be detailed at that time

If the data monitoring process and/or site visit identifies an unacceptable level of errors or egregious violation of Registry policy, the Registry Advisory Panel will be notified and a corrective action plan will be implemented.

10. Reports

Participating sites can generate and export their own patient Registry data via simple reports using the SJCARES Cancer Registry Platform system on a routine basis. A report of Registry activity will be provided by the St. Jude Global Registry Team quarterly, which summarizes Registry activity to date in addition to individual site statistics. These quarterly reports will be shared with sites that have been actively entering data into the system (PROD) in the prior 3 months.

If a site needs access to specific Registry use data at other times, the MD Monitor should contact the SJ CRA at registry@stjude.org with details of the request. The site should plan for up to 4 weeks for the requested report to be provided.

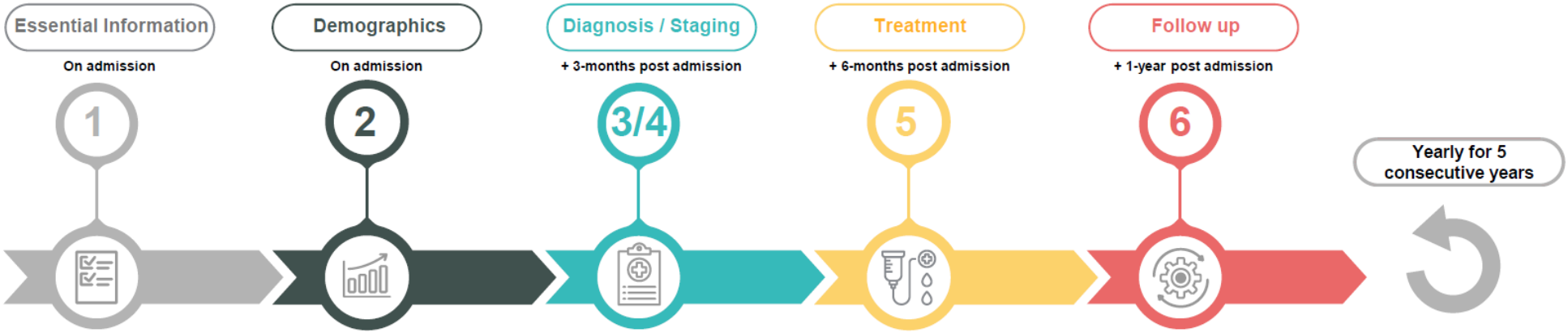
11. User's Manual Maintenance

This User's Manual will be reviewed at least annually by the SJ CRA for accuracy and completeness. Additional changes may be appropriate at other times. Whenever the User's Manual is changed, the current Registry sites will be notified by email with a summary of the item(s) that have been changed and a current copy of the User's Manual. The site is expected to maintain access to the most current version of the User's Manual and implement any updates immediately upon receiving the new User's Manual.

Section Two: Overview of Data Collection

1. Overview of the Data Elements in the iCRFs

This figure outlines the timeline of data entry and an overview of the data elements captured on the 5 main iCRFs of the SJCARES Cancer Registry. This figure does not include every data element on each form due to the extensive branching logic built into the iCRFs.



1. SJCARES ID
2. First & Last name(s)
3. Date of birth
4. Gender
5. Reporting a second cancer on a previously registered patient

1. National ID number (unique identifier)
2. Medical Record Number
3. Race/Ethnicity
4. Parent/Primary Caregiver´s name
5. Highest education (parent/caregiver)
6. Contact information

1. Date of initial Onset of cancer-related symptoms
2. Date of first medical Assessment for cancer
3. Confirmed cancer diagnosis
4. Date of diagnosis
5. Method of diagnosis
6. ICD-O-3 Topography & Morphology
7. Laterality of primary site
8. HIV status
9. Referral source
10. Class of case
11. Place of diagnosis (site name/city/country)
12. ICCC3 extended classification code
13. Toronto tier 1, 2, +2 (as applicable)
14. CNS involvement (if applicable)
15. Peripheral white blood count

1. Date of referral to treatment institution
2. Date patient started treatment
3. Type of treatment and treatment details (site where it was given, exclusively at site, partial Treatment, palliative Treatment, active surveillance, no treatment given)
4. Type of palliative treatment delivered (if applicable)
5. Therapeutic Protocol ID
6. Treatments administered since diagnosis (Chemo, radiation, surgery, stem cell transplant, retinoblastoma treatment, pain management treatment)

1. Disease status (remission/relapse/inactive disease)
2. Cancer-directed treatment (entirely at site)
3. Treatment(s) delivered curative/palliative/no treatment given)
4. Treatment details (chemo, radiation, surgery, stem cell transplant, retinoblastoma treatment, pain management treatment)
5. Vital status (last known vital status- Alive/Dead/Treatment abandonment/unknown)
6. End of treatment date (if applicable)
7. Date of last follow up
8. Vital status source/method of contact
9. In the event of death- Cause of death (primary & secondary), location and date of death

1.1. Customizable Country-Specific Site Worksheet

The participating St. Jude Global Alliance member who has requested an SJCARES Cancer Registry user account will be provided with the required Worksheet to complete via Qualtrics. Once completed answering questions about the local site/institution, including National ID information and racial and ethnic groups, the Alliance member will submit the Worksheet back to St. Jude Global. The provided information will be used to tailor the Registry platform to make fields relevant for in-country Alliance participants and end-users.

2. Data Fields of the SJCARES Cancer Registry

2.1. Form 1: Essential Information

1. Essential Information	The Essential Information form should be completed on Day 0, or the admission (inpatient or outpatient) date.		
Field	**Description**	**Comments**	**Special case scenarios**
First Name*	Registered patient's first name.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Last Name*	Registered patient's last name.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Middle name/Alternate family name	Registered patient's middle or alternative family name.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Date of Birth*	The birth date of the patient. Date format DD/MM/YYYY [this format applies to all date fields].	This data is completed once, as soon as the patient is identified for inclusion in the registry.	
Gender*	The biological difference between male and female, represented by a code.	This data is completed once, as soon as the patient is identified for inclusion in the registry.	
SJCARES ID	Unique ID (random assignment by system) assigned to each unique patient.	Automatically generated by the system. Cannot be edited by the user.	NOTE: the SJCARES ID numbers assigned to patients may NOT be consecutive (e.g., you may have a patient with ID 00010008 and your next patient may be 00010012).
Date of Registration	-For patients with a date of diagnosis more than 5 years prior to the day you are entering the patient into the Registry, leave this field blank. -For patients with a date of diagnosis within 5 years from the day you are entering the patient, enter in the date the		If your hospital joined the Registry in January 2023 and are entering in a patient that was diagnosed in 2015, you should leave this Date of Registration field blank.

	patient was first seen at your hospital. -For current patients (current year and beyond) enter in the date the patient was first admitted to your hospital (if this information is available) or use the date that you begin filling out the Essential Information form.		
Are you attempting to report a second cancer in a patient who was previously registered?	Do not answer unless prompted after clicking "complete" on the Essential Information form	YES: answer the subsequent question that appears NO: answer the subsequent question that appears	
These cases will now be linked in the Registry and a new SJCARES ID will be assigned for the patient's second cancer. Confirm or Cancel?	Appears if "YES" to "Are you attempting to report a second cancer in a patient who was previously registered?"	CONFIRM: save the form as complete CANCEL: answer the subsequent question that appears	
Confirm the SJCARES IDs represent different persons.	Appears if "NO" to "Are you attempting to report a second cancer in a patient who was previously registered?" or "CANCEL" to "These cases will now be linked in the Registry and a new SJCARES ID will be assigned for the patient's second cancer. Confirm or Cancel?"	YES: save the form as complete NO: the system will not allow the patient record to be saved because it recognizes it as a duplicate. Please review the answers to the previous question(s) and confirm the responses are accurate.	If any questions, please reach out to registry@stjude.org for assistance.

* Indicates a required field

2.2. Recurring form: eCRF Completion

eCRF Completion An eCRF completion form will appear with each CRF moving forward: Demographics, Diagnosis, Staging, Treatment, and Follow-up Years 01-05.			
Field	**Description**	**Comments**	**Special case scenarios**
Phase	This field contains the name of the form corresponding to the eCRF completion form: Demographics, Diagnosis, Staging, Treatment, Follow-up Year 1-5.	Automatically populated. This field is grayed out and cannot be edited.	
Date of eCRF Completion*	Record the date that you begin filling out the corresponding eCRF form (e.g., Demographics, Diagnosis, Staging, Treatment, Follow-up).	An eCRF Completion form will appear before each CRF (i.e., Demographics, Diagnosis, Staging, Treatment, and Follow-up Year 1-5).	

* Indicates a required field

2.3. Form 2: Demographics

2. Demographics	The Demographics form should be completed on Day 0, or the admission (inpatient or outpatient) date		
Field	**Description**	**Comments**	**Special case scenarios**
National ID*	Based on registration system unique to each country but different from Reference ID to link patient to their medical records	St Jude staff will not have access to this variable field.	*Not applicable* checkbox option
Medical record number*	Unique pseudonymized reference ID linked to a patient identifier at the SITE registering patient. Can be used to link patient to their local records.	Reference ID for primary hospital to link to their records such as a medical record number. St Jude staff will not have access to this variable field.	
Address Line 1*	The street name and number that identifies the usual physical place of residence (street number and name) of a patient.	Field visible only to site. St. Jude staff will not have access to this variable field.	Note: Do not come back to this form to update this information; there is an opportunity to update address and contact information in the Follow-up iCRFs. Keep the original data here and enter new information on the appropriate follow-up form.
Address Line 2-4	Additional information that identifies the usual physical place of residence of a patient.	Field visible only to site. St. Jude staff will not have access to this variable field.	
City	The name of the city that identifies the usual physical place of residence of a patient.	Field visible only to site. St. Jude staff will not have access to this variable field.	
State/Province	The name of the state or province that identifies the usual physical place of residence of a patient.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Region	The region where the usual physical place of residence of the registered patient is.	Field visible only to site. St. Jude staff will not have access to this variable field.	

Country	The country in which the registered patient lives or intends to live for six months or more.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Race*	Code the patient's race.	Each institution will provide a unique list, on Appendix III, based on the appropriate country census designations.	
Ethnic Group*	Code the patient's ethnicity.	Each institution will provide a unique list, on Appendix III, based on the appropriate country census designations.	
Parent/Primary Caregiver Name*	First and last name of patient's mother, parent, guardian, or primary caregiver. Refers to the individual who is to be contacted for the patient's follow-up.	Field visible only to site. St. Jude staff will not have access to this variable field.	*Not applicable* checkbox option
Parent/Primary Caregiver Highest Education*	The highest level of education achieved by either parent, guardian, or primary caregiver of the patient; again, refers to the individual who is to be contacted for patient follow-up.		If the caregiver's Highest Education level is not known or this information is not available, select "Unknown" in the dropdown menu.
Best Phone Number(s) to Contact Patient/Caregiver*	Best phone number(s) to contact family and/or patient, for the purposes of follow-up. Can include family friends or relatives.	Field visible only to site. St. Jude staff will not have access to this variable field.	
Best E-mail(s) to Contact Patient/Caregiver*	Best e-mail address(es) to contact family and/or patient, for the purposes of follow-up. Can include family friends or relatives.	Field visible only to site. St. Jude staff will not have access to this variable field.	

* Indicates a required field

2.4. Form 3: Diagnosis

3. Diagnosis		The system expects the Diagnosis form to be completed 3 months after Day 0.	
Field	**Description**	**Comments**	**Special case scenarios**
Date of Initial Onset of Cancer-Related Symptoms*	Date the patient began to experience symptoms and signs related to cancer.	If the exact date is unknown, enter approximate date (XX/XX/YYYY or XX/MM/YYYY). A year is always required. When the information is available, entering a year and month is highly preferred.	
Date of First Medical Assessment for Cancer Associated Symptoms*	Date the patient first sought primary care for cancer-related symptoms at any hospital/clinic with a healthcare provider prior to admission.	If the exact date is unknown, enter approximate date (XX/XX/YYYY or XX/MM/YYYY). A year is always required. When the information is available, entering a year and month is highly preferred.	Example: a patient goes to community clinic for fatigue and slightly swollen lymph nodes, and after symptoms continue, they decide to go their primary care physician (PCP). The patient's PCP refers them to the local hospital. What day should be reported here? **Answer**: the date they were seen at the community clinic as that was the first day they sought care for cancer-related symptoms.
Does patient have a confirmed cancer diagnosis?*	Confirmation of a cancer diagnosis, whether clinically or microscopically, by a recognized medical practitioner.	YES: answer the subsequent questions that appear regarding the diagnosis NO: answer the subsequent question that appears	If you select NO, data collection will end with the Diagnosis form (i.e. you will not complete Staging, Treatment, or Follow-up forms for non-cancer diagnoses). For benign CNS tumors: answer YES to this question and continue to classify the diagnosis using ICD-O codes. These should then classify into ICCC-3 III (CNS tumors) and Xa (Germ cell tumors of CNS).

			For all other benign, non-malignant tumors, you would not report.
What is the patient's non-cancer diagnosis?*	Open-ended, free text annotation of non-cancer diagnosis.	Only appears when NO to "Does patient have a confirmed cancer diagnosis?"	
Date of Diagnosis*	Date of initial diagnosis, whether clinically or microscopically confirmed, by a recognized medical practitioner.	The first event in the hierarchy below should be selected: 1) The date the patient was evaluated for suspicion of cancer. 2) The date you begin the clinical workup for a patient when a biopsy isn't needed. 3) The date that you initiated treatment due to an oncological emergency or due to diagnostic delays. 4) The date that the biopsy was ordered. 5) The date that the biopsy was performed. 6) The date histopathology report was officially issued, if none of the above are available or apply. The "XX/XX/YYYY" and "XX/MM/YYYY" format **cannot** be used for this data field, as it is used to calculate the Age of Diagnosis. If the exact date is unknown, enter "01" as the day (DD) of the month, followed by the month and year.	Example 1: biopsy is performed and sent to pathology for diagnostic analysis. What date should be reported as the date of diagnosis, the day of the biopsy procedure or the date of the histopathology report? **Answer**: Date of the biopsy procedure Example 2: patient comes into your hospital reporting knee pain and a swollen knee. The ER doctor suspects cancer and refers the child to a specialist and a CT scan and biopsy are both performed later that week. What day should be reported as the date of diagnosis? **Answer**: the date the ER physician suspected cancer.
Age at Diagnosis (years)	Automatically generated based on patient's date of	Automatically generated-- there is no data entry needed here as this data	

	birth and date of diagnosis; age appears in years (in whole numbers).	field is grayed out. Take note of this calculated date; if the age shown in this field is different from what is known from the medical record, then an error has occurred in one of the data entries.	
Best Method of Diagnosis Used*	Select the best method that was used for diagnostic confirmation of the cancer being reported prior to starting treatment.	The highest in the hierarchy should be selected if multiple diagnostic methods were used [autopsy/death certificate>microscopic verification>exploratory surgery>imaging (CT, MRI)>lab exams>clinical examination]. Please note that in some early-stage solid tumors, the microscopic verification of the cancer being reported is expected AFTER a therapeutic tumor resection is done. In these scenarios, still select the best method used prior to initiating therapy. For example, Wilms tumors or Retinoblastoma would be diagnosed by imaging or clinical examination, respectively. This is appropriate and should be documented as such.	Example: a patient was clinically examined, had labs, and had a biopsy with results sent back from the histology department. In this example, the best method used would be (5) "Microscopic Verification" (see below for hierarchy with 1 being the least and 6 being the most conclusive). (6) Autopsy/death certificate (5) Microscopic verification [including cytology, histology, hematology (e.g. blood/bone marrow smear and/or flow cytometry for immunophenotyping and/or cytogenetics and/or molecular biology) (4) Exploratory surgery (without specimen/biopsy) (3) Imaging (2) Lab exams (including tumor markers, complete CBC, liver panel, etc.) (1) Clinical examination
Topography/Site*	Codes for the topography/site of the tumor being reported using ICD-O-3.	Subsequent data fields of Morphology and the ICCC-3 Extended Classification Code are filtered based on the response to this Topography/Site data field. When searching the Topography/Site, medical terms will be listed with synonyms listed in parenthesis (the	If the patient was diagnosed at another hospital (i.e. the referring hospital), but further testing at the reporting hospital shows a different, or more refined, diagnosis, then the most accurate diagnosis should be entered in to the iCRF. You have up to 3 months after

		synonyms may include both medical and lay terms). When searching terms, the system will filter the options based on what you are typing (for both medical terms and synonyms).	originally registering the patient to verify and enter the diagnostic information. If the diagnosis needs to be changed for any reason, the user will be prompted to enter the reason as to why the change is being made when entering the updated data. Example: a patient is first seen by a doctor at another hospital and then is seen by a doctor at your hospital. The diagnosis at the first hospital was reported to be Non-Hodgkin's Lymphoma but after further testing at your hospital, the patient's diagnosis was confirmed to be non-differentiated nasopharyngeal carcinoma. What diagnosis should be reported? **Answer**: the final, confirmed diagnosis, non-differentiated nasopharyngeal carcinoma When entering the diagnosis, if the morphology is known, but the specific site is not, then select the appropriate NOS topography code. The NOS codes have "unknown" as synonyms so you can use the search tool and select the appropriate NOS code from the filtered options.
Morphology: Type & Behavior Code*	Codes for the histologic type and behavior of the tumor being reported using ICD-O-3.	The options available in the field are dependent on the ICD-O-3 Topography coded. The data entered in to this field influences the value that auto-populates the ICCC-3 Extended Classification Code data field.	Case scenario: A patient presented with a mass in his paravertebral area. Upon further testing, the reporting hospital diagnosed the patient with embryonal rhabdomyosarcoma. When entering the topography, "Vertebral column" does

		Although standard ICD-O-3 formatting includes a "C," the letter has been omitted from the codes on the SJCARES Cancer Registry.	not generate "Embryonal rhabdomyosarcoma" as an option under the morphology dropdown menu (see Figure 1). However, entering "Nervous system, NOS" generates the correct morphology, "Embryonal rhabdomyosarcoma" (see Figure 2). *To ensure data accuracy and quality in terms of diagnosis and staging, be sure to utilize synonyms to be certain the appropriate morphology selection is available/appears.*
ICCC3 Extended Classification Code	Automatically generated based on combination of ICD-O-3 topography and morphology codes.	Automatically populated. No data entry is required for this data field. ICCC-3 classification has implications on the Staging of the cancer, so it is important that the topography and morphology be coded properly so that the correct ICCC-3 classification is generated. This will also appear on the Staging iCRF.	
Laterality of primary site*	Code for the side of a paired organ, or the body on which the reportable tumor originated. This applies to the ***primary site of the neoplasm only.***	The system filters the options that are appropriate for the diagnosis that is entered. If you do not see an option that reflects the laterality reported in the patient's medical records, go back and double check proper transcription of the topography and morphology.	Why does the "Laterality of Primary Site" data field automatically fill to "Not a paired site"?: This field will automatically populate when the topography selected is not a paired site and thus laterality is not applicable.
HIV Status*	Code for the indication of Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS). If there is no mention of HIV/AIDS in	If you select the option "HIV positive" in the dropdown menu for HIV Status, the system will then ask you to provide the Date of HIV+ Test.	

	patient medical record, select "HIV status not assessed or unknown if assessed."		
Date of HIV+ test*	Code the date the patient was tested for HIV and the result was positive.	If the exact date is unknown, enter approximate date (XX/XX/YYYY or XX/MM/YYYY).	
Referral Source*	Codes the earliest source of identifying information for who sent the patient to the hospital or site. For cases identified by a source other than reporting facilities (such as through death clearance or result of an audit), this variable codes the type of source through which the tumor was first identified.	Reporting Hospital refers to your hospital. If "Outside Hospital/Clinic" is selected, more information is required about that hospital/clinic (e.g. name and address of the facility)—answer subsequent questions that appear.	If a patient is referred from another hospital/clinic, register that hospital/clinic as the Referral Source.
Outside Hospital/Clinic specify*	This field identifies the Outside Hospital/Clinic referral source.	Carefully review the answer choices to be sure the specific department or referral source is not already listed before selecting the option "Other Hospital Source, Specify." Please note in the rare instance that you select "Other Hospital Source, Specify," you will be asked to provide the information for the alternate referral source.	
Specify	Provide the information for the alternate referral source.	Open text field	
Class of Case*	This field distinguishes cases that are usually included in a hospital's treatment and	The Class of case selections are filtered down based off of the referral source provided.	Please see Appendix D for examples.

	survival statistics from those that are not.		
Place of Diagnosis-Name*	Name of hospital/facility where the patient was first clinically diagnosed with cancer.		
Place of Diagnosis*	Information for the hospital/facility where the patient was first clinically diagnosed with cancer.	Includes the following data fields: Country*, City*, State/Province, Region, Address line 1*, Address line 2. These fields only appear if Referral Source is reported as Outside Hospital/Clinic.	If they come to you with a diagnosis from another hospital/clinic and that is the diagnosis your hospital uses for treatment decisions, record the other hospital/clinic as the Referral Source *and* the Place of Diagnosis. If they come with a diagnosis and your hospital does the diagnosis again, record your hospital's name as Place of Diagnosis. If they are referred to your hospital without a diagnosis and you do the diagnosis at your hospital, record your hospital as the Place of Diagnosis.

* Indicates a required field

2.5. Form 4: Staging

4. Staging		The system expects the Staging form to be completed 3 months after Day 0.	
Field	**Description**	**Comments**	**Special case scenarios**
ICCC3 Extended Classification Code	Automatically generated based on combination of ICD-O-3 topography and morphology codes.	Automatically populated. No data entry is required for this data field.	Note: if you update the diagnosis [topography and morphology], the ICCC3 Extended Classification code may also change, this is automatically done by the system. If the ICCC3 code changes, the staging form will also update and need to be completed for the updated diagnosis.
Stage -Is there central nervous system involvement? -Toronto Tier 1 -What is the patients peripheral white blood cell count (as measured by patients peripheral blood sample) at diagnosis? (microliters) -Not reported -Was chemotherapy received prior to surgery? -Toronto Tier 2 -Symptoms -Designation -Toronto Tier 2+	This item stores the results of clinical stage groupings based on the Pediatric Cancer staging guidelines and consensus. The dropdown menu will be based on diagnostic group/subgroup.	The system uses ICCC3 extended classification codes to generate the appropriate staging form per patient. That is, the system uses the information the Data Entry Specialists enter for childhood cancer diagnosis to only provide the staging questions applicable to the patient's specific diagnosis. The ICCC3 data field auto-populates and the iCRF generated asks the questions relevant to the diagnosis and corresponding staging system. Refer to Appendix IV in the Data Dictionary document for the staging system map and the disease specific staging coding rules (adapted from the Toronto Guidelines on Pediatric Cancer Staging).	Note: you will record the INITIAL staging on the staging form. If the patient's cancer starts as localized and then metastasizes, you will NOT go back to the staging form to update from localized to metastatic. This form is intended to capture the initial staging. For patients with leukemia: The first staging question will be "Is there central nervous system involvement?" Once you answer the CNS question the system will prompt you to enter in the Toronto Tier 1 stage. Additionally, enter in the patient's white blood cell count (in microliters) or

			select ‘Not reported’ if the data is unavailable or not applicable.
Toronto Tier 2 Staging Description	Text descriptions corresponding to the Toronto Tier 2 stages.	Text will only appear in this box when appropriate (i.e., when a Tier 2 Stage is selected).	
Comments	Open ended, free text annotation of cancer staging.	Do NOT include Protected Health Information (PHI) in this field.	

* Indicates a required field

2.6. Form 5: Treatment

5. Treatment		The system expects the Treatment form to be completed 6 months after Day 0. This form should be completed one time to capture INITIAL treatment given.	
Field	**Description**	**Comments**	**Special case scenarios**
Date of Referral to treatment Institution*	Date of when the patient came into the reporting site for the first consultation, inpatient admission or outpatient clinic.	This date cannot be before date of birth, date of cancer symptoms onset, or date of first medical assessment for cancer associated symptoms. Additionally, the formats "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field, meaning an expected date is not a valid entry for this data field.	
Treatment with curative intent given ENTIRELY at your site?*	Records whether treatment with curative intent was administered at the reporting site. NOTE: this question does NOT pertain to completing the entirety of therapy, but rather the place of where the patient received therapy.	YES: Answer subsequent questions that appear NO: Provide a reason why treatment not given Unknown: No further information needs to be entered	If a patient comes to your hospital after starting treatment at another hospital, select NO and choose "patient treated PARTIALLY at another center" in the dropdown that appears. Provide the details for the hospital where treatment was started and then register the treatment previously provided as well as the treatment the patient is receiving at your hospital under "treatments administered since diagnosis." If a patient is treated only at one institution, but dies early in treatment, the answer to this question is YES.
Date curative treatment started *	Date of the inpatient admission or outpatient clinic at **the reporting site** to start definitive treatment.	Date cannot be before the date of birth. Additionally, the formats "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field	If a patient has surgery and chemotherapy within the first 3 months of treatment at your site, you should record the date the patient

			first received any cancer directed treatment.
Is the patient being treated on a therapeutic protocol?*	Records whether patients are treated on a clinical treatment protocol with a specific reference name and ID.	YES: enter the Protocol details or ID in the field that appears NO: Proceed to next question	
Protocol details or ID*	Details of the specific treatment protocol name/ID.		
Treatments administered since diagnosis: * Did the patient receive chemotherapy? Did the patient receive radiation? Has the patient had cancer tumor directed surgery? Has the patient had a hematopoietic stem cell transplant? Has the patient had any retinoblastoma-specific treatments?	Records whether patients are initially treated with chemotherapy, external beam/other radiation, surgery, hematopoietic stem cell transplantation, retinoblastoma-specific treatment types, and palliative pain/symptom management.	YES: check the box for each applicable chemotherapy medication, radiation site, surgery type, stem cell transplant type, and/or retinoblastoma-specific treatment. NO: Proceed to next question Retinoblastoma-specific treatment question ONLY appears if corresponding morphology [retinoblastoma] is recorded on Diagnosis form. a. When selecting "Other," you have to check the box in the second column and then specify to the right. b. Do NOT enter dosage amounts or dates into the "Other" data field. This is not a place for dosage of radiation. c. Appropriate entries into the "Other" data field include the full chemotherapy	It is important to remember that the treatment form is for capturing the first treatment(s) given to the patient. For example, a patient has been registered in the Registry and has complete Diagnosis and Staging iCRFs, the patient was given chemotherapy and had surgery within the first three months post-diagnosis, then both should be recorded on the Treatment iCRF in the Registry. If the patient had the chemotherapy within 3 months of diagnosis but didn't have surgery scheduled until after the 6-month timeframe, then the surgery would be captured on the appropriate Follow-up Form. A patient diagnosed with osteosarcoma has an amputation of their right leg at his femur, how should this surgery be reported in the Registry? **Answer:** an amputation

		medication name and anatomical locations where the radiation was administered for Chemotherapy and External Beam/Other Radiation options, respectively. Be sure to carefully look at the provided options as to not provide redundant information in the "other" field.	should be reported as "gross-total resection plus removal of adjacent structures"—in this patient example, amputating the patient's leg at the right femur will also result in the removal of the patient's right knee and lower part of the leg as well.
Reason treatment not given*	Records the reason treatment with **curative** intent was not administered at the reporting site.	Select the appropriate response from the dropdown menu.	If "Patient treated ENTIRELY at another center" or "Patient treated PARTIALLY at another center" are selected, provide Center Details as prompted.
Center details*	Treatment center details.	Name of Center, Country, Address line 1, Address line 2, City, State/Province Appears when "Patient treated ENTIRELY at another center" or "Patient treated PARTIALLY at another center" are selected for "Reason treatment not given"	
Treatments Administered at Other Center	Records which type of treatment (Chemotherapy, Radiation, Cancer tumor directed surgery, Hematopoietic stem cell transplant, Palliative pain/symptom management specific treatment, Retinoblastoma-specific treatment, Unknown) the patient received at the other center.	Check the box of the type(s) of treatment that were administered to the patient at the other center when the patient is PARTIALLY treated elsewhere.	Example: If a patient received chemotherapy at the reporting hospital and radiation at another center, the Radiation checkbox should be selected.
Type of palliative therapies delivered?*	Records whether palliative treatment was	This question appears when "Reason treatment not given" is selected as	

	administered at the reporting site.	"Patient treated for palliative purposes as curative treatment not feasible"	
Has the patient had any palliative pain/symptom management?*	Records the initial palliative treatment types administered at the reporting site.	YES: check the box for the applicable palliative pain/symptom management treatment administered. NO: Proceed to the next question	

* Indicates a required field

2.7. Form 6: Follow-up

6. Follow-up	The system expects the first Follow-Up form to be completed 12 months after Day 0, and yearly after. NOTE: if a patient is reported as "Dead" or "treated ENTIRELY at another center" prior to Follow-up Year 05, the subsequent Follow-up forms will be hidden, and no further forms will need to be completed.		
Field	**Description**	**Comments**	**Special case scenarios**
Has the patient achieved known/confirmed remission (no evidence of disease) since diagnosis?*	Record of the patient's cancer remission or inactive disease status. To be obtained at each evaluation.	YES: provide date of remission and answer the subsequent question that appears. NO: end of logic. Move to the next section.	If not confirmed, or *unknown*, or if you haven't seen the patient in the current year of Follow-up, you should answer "NO" to this question.
Date of Remission*	The date complete remission (inactive disease or no evidence of disease) was achieved since or after diagnosis.	Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field. If the exact date is unknown, use "01" for the day and enter the appropriate month and year in the data field.	
Has the patient had a known/confirmed relapse/recurrence since remission? *	Record of the patient's relapse or recurrence status.	YES: provide the date of relapse/recurrence and answer the subsequent question that appears. NO: end of logic. Move to the next section.	
Date of Relapse/Recurrence*	The date relapse/recurrence occurred.	Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field. If the exact date is unknown, use "01" for the day and enter the appropriate month and year in the data field.	
Has the patient achieved known/confirmed remission since relapse/recurrence? *	Record of the patient's remission or inactive disease status since prior relapse/recurrence.	YES: provide the date of remission and answer the subsequent question that appears. NO: end of logic. Move to the next section.	
Date of Remission*	The date complete remission (inactive disease	Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot	

	or no evidence of disease) was achieved since or after relapse/recurrence.	be used for this data field. If the exact date is unknown, use "01" for the day and enter the appropriate month and year in the data field.	
Has the patient had a known/confirmed relapse/recurrence since remission? *	Record of the patient's relapse/recurrence status since prior remission.	YES: provide the date of relapse/recurrence and move to the next section. NO: end of logic. Move to the next section.	
Date of Relapse/Recurrence*	The date relapse/recurrence occurred.	Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field. If the exact date is unknown, use "01" for the day and enter the appropriate month and year in the data field.	
Is the patient STILL in remission (no evidence of disease)? *	Record of whether or not the patient is still in complete remission or inactive disease status since the last follow-up timepoint.	This field will only appear on forms after Remission status has been achieved.	
Has the patient received cancer-directed treatment ENTIRELY AT YOUR SITE since the last data entry? *	Specify if the patient has had any treatment since the last time data was entered, and if so, select the types of treatments (curative, palliative, or both) given in the interval since last update to the Registry.	YES: Answer subsequent questions that appear NO: Provide reason why treatment not given Unknown: No further treatment information needs to be entered	Follow-up form year 1 captures any treatment since the initial treatment captured on the Treatment iCRF, which can include changes to treatment that occurred in the first year since starting treatment.
Curative treatment given	Records if patient received curative intent treatment.	Check the box to record curative treatments given.	Note: both curative and palliative boxes can be selected on the same form, if appropriate. For example, the patient started on curative therapy but then 9

			months through year 1, the patient also had palliative therapies added. Follow-up form year 1 would have both curative and palliative treatment given selected.
Palliative treatment given	Records if patient received palliative treatment.	Check the box to record palliative treatments given.	
Treatments administered since last completed follow-up: * Did the patient receive chemotherapy? Did the patient receive radiation? Has the patient had cancer tumor directed surgery? Has the patient had a hematopoietic stem cell transplant? Has the patient had any retinoblastoma-specific treatments?	At each follow-up, please select all treatments with curative intent given in the interval since the last registry update. Records whether patients are treated with chemotherapy, external beam/other radiation, surgery, hematopoietic stem cell transplantation, retinoblastoma-specific treatment types.	YES: check the box for each applicable chemotherapy medication, radiation site, surgery type, stem cell transplant type, and/or retinoblastoma-specific treatment. NO: Proceed to next question. Retinoblastoma-specific treatment question ONLY appears if corresponding morphology [retinoblastoma] is recorded on Diagnosis form.	If a patient has exploratory surgery for a new tumor during any of their follow-up periods, does this get included as a type of curative treatment administered or 'cancer tumor directed surgery'? **Answer:** No, since we are capturing pediatric cancer cases, the follow-up forms are asking about treatment administered and directed towards the pediatric cancer diagnosis recorded on the prior Diagnosis iCRF. As the surgery could be diagnostic, it is important to differentiate between a diagnostic surgery and a therapeutic surgery. Additionally, if a patient has a non-cancer related surgery, like an appendectomy (i.e. removal of the appendix), there is no need to record this as a surgery on the Treatment or Follow-up forms; you would answer 'no' to the

			question regarding cancer tumor directed surgery.
Type of palliative therapies delivered? *	At each follow-up, please select the type of palliative treatment given in the interval since the last data entry in the Registry.	Select the appropriate option from the dropdown menu.	
Has the patient had any palliative pain/symptom management specific treatment?*	Records if the patient received any palliative (pain/symptom) management specific treatment in the time interval since the last data entry in the Registry.	YES: check the box for the applicable palliative (pain/symptom) management treatment administered. NO: Proceed to the next question	
Curative treatment not given at follow-up, reason*	Records the reason curative treatment was not given.	Select why curative therapy not pursued during follow-up period.	
Center details*	Treatment center details.	Name of Center, Country, Address line 1, Address line 2, City, State/Province Appears when “Patient treated ENTIRELY at another center” or “Patient treated PARTIALLY at another center” are selected for “Curative treatment not given at follow-up, reason”	
Treatments Administered at Other Center	Records which type of treatment [Chemotherapy, Radiation, Cancer tumor directed surgery, Hematopoietic stem cell transplant, Palliative (pain/symptom) management specific treatment, Retinoblastoma-specific	Check the box of the type(s) of treatment that were administered to the patient at the other center when the patient is PARTIALLY treated elsewhere.	If a patient received chemotherapy at the reporting hospital and radiation at another center, the Radiation checkbox should be selected.

	treatment, Unknown] the patient received at the other center.		
Last known vital status*	Specifies the vital status (dead, alive, not seen since last follow up, or unknown) of the patient at the last date of last contact.	Dead: answer subsequent data fields that appear [Date of death, Cause of Death, Place of Death] Alive: provide date of last follow-up Not seen since last follow up: move to next question. Unknown: provide date of last follow-up	If a patient abandons treatment within the first year: you should record the vital status as "Unknown" and record the date that you last had contact with the patient as the "Date of last follow-up." If the patient abandons treatment Follow-up Years 2-5: record the patient's vital status as "not seen since last follow up." Note: make sure to complete all 5 years of follow-up even when the patient has not been seen since last follow up. Two scenarios where follow-up may be less than 5 years are in cases of patient death or if the patient left the reporting hospital to be treated ENTIRELY at another center.
Date of death*	Records the date of death of the patient.	This data filed will appear when vital status is recorded as "Dead." Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field. If the exact date is unknown but month and year are known, use "01" for the day and enter the appropriate month and year in the data field.	If I call a patient to schedule their follow-up appointment and the caregiver reports the patient died, what date do I put as the Date of Death? **Answer:** if the exact date of death is unknown, but an approximate date is able to be determined, record the approximate date; for example, the caregiver reports the patient died 2 weeks ago, calculate two

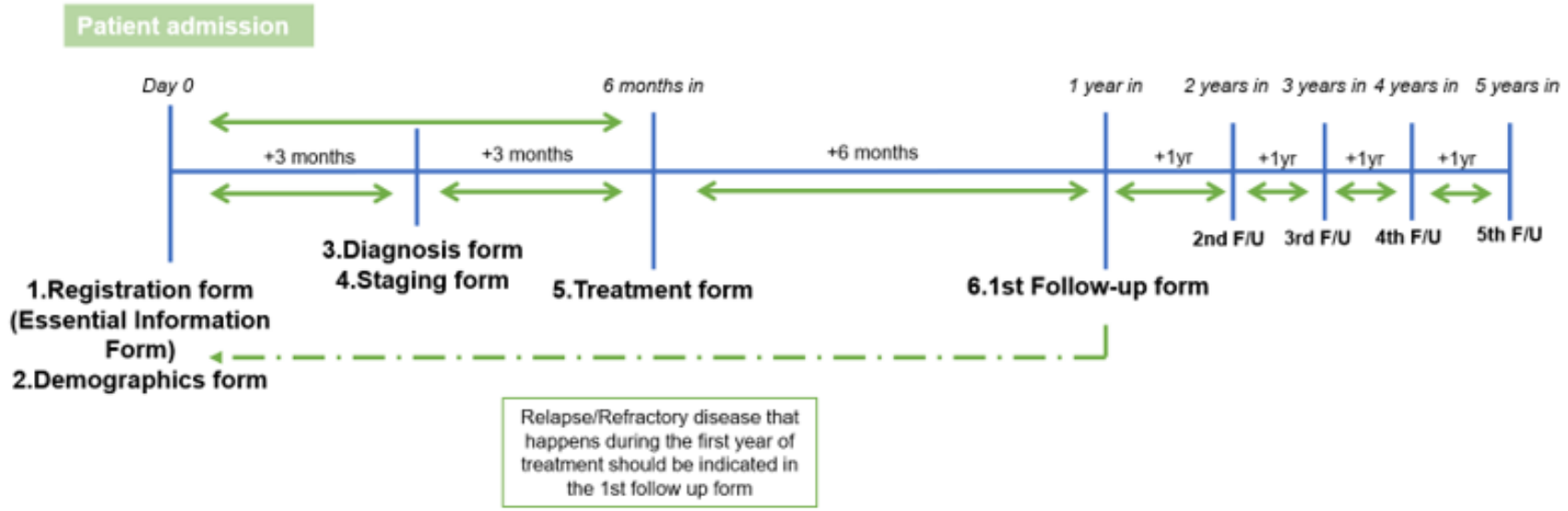
			weeks prior and record that date as Date of Death. If the exact or approximate date cannot be determined, use 01 as the date and enter in the appropriate month and year. When a month is also unknown, submit a Bypass note in the system and write a note regarding the missing date; if you know the year of the patient's death, you can include it in the Bypass note. [See Appendix B for details on how to submit a Bypass note.]
Date of last follow-up*	The date of last contact with the patient.	This data field will appear when vital status is recorded as "Alive" or "Unknown." This date will show up next to the iCRF name in the left side bar. Expecting date values of the format "XX/MM/YYYY" and "XX/XX/YYYY" cannot be used for this data field. If the exact date is unknown but month and year are known, use "01" for the day and enter the appropriate month and year in the data field.	
Source of vital status or method of contact data*	Specifies the source of information regarding the patients' vital status.	"Outside clinician" refers to a medical professional located outside of the reporting hospital, or your site. "Death certificate" should not be selected if the last known vital status was recorded as "Alive." If so, you will receive an error message.	

Specify*	Record the source of vital status or method of contact data	This field appears if you select “Other” as the Source of vital status or method of contact data.	
Cause of Death Primary* Secondary Tertiary Quaternary	Official cause of death information as coded from the death certificate or best available information in the WHO application of ICD-10 codes for low-resource settings initial cause of death collection document. Cancer-related deaths are linked to ICCC3 extended classification codes. Primary cause of death refers to the disease or injury which initiated the sequence of morbid events leading directly to death.	The magnifying glass icon allows you to search CodeList options.	
Place of Death: Country*	Records the country where the patient died and where certificate of death is filed.		If this information is not known, select UNKNOWN at the bottom of the dropdown menu.
Place of Death: Location*	Records the specific place where the patient died and where certificate of death is filed.		If this information is not known, select UNKNOWN at the bottom of the dropdown menu.
Does the patient’s contact information need to be updated?*	Confirmation of an update(s) to the patient’s contact information for the purposes of follow-up.	YES: select which information needs to be updated [Address, phone, email] NO: save the form as complete Field visible only to site. St. Jude staff will not have access to this variable field.	
Address Address line 1*	Record the patient’s updated primary address.	If you check the box, complete the subsequent fields that appear.	

Address lines 2-4 City State/Province Region Country			
Phone Best Phone Number(s) to contact patient/caregiver*	Record the patient/caregiver's updated phone number.	If you check the box, complete the subsequent field that appears.	
Email Best E-mail(s) to Contact Patient/Caregiver*	Record the patient/caregiver's updated email address.	If you check the box, complete the subsequent field that appears.	
Comments	Open ended, free text annotation of cancer relapse/recurrence, remission, treatment, case finding activities, and follow-up.	Do not include Protected Health Information (PHI) in this data field.	

* Indicates a required field

Appendix A. Data Entry Timeline

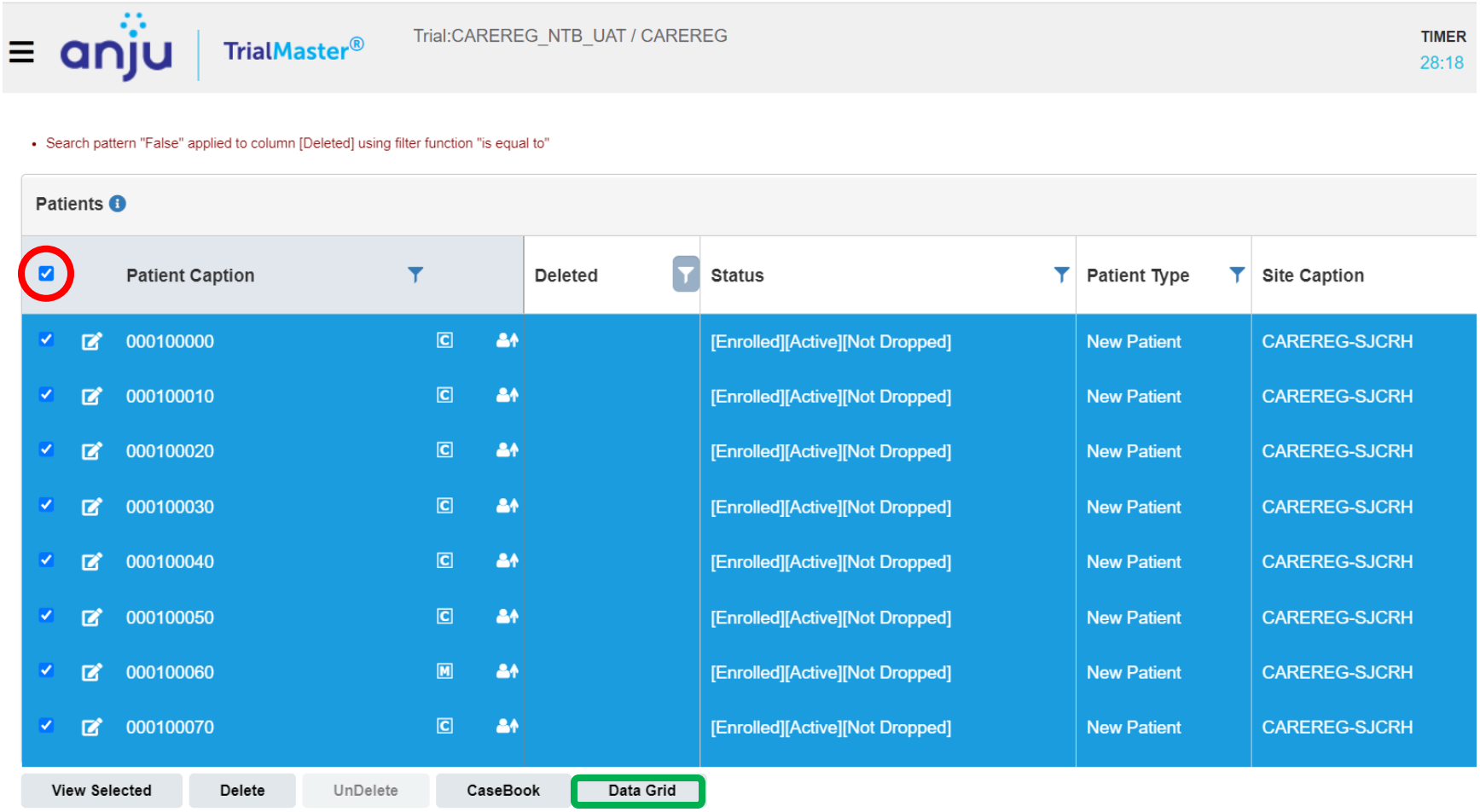


This timeline outlines how the data should be collected and entered into the Registry. Day 0 is the date the patient's timeline begins and the Essential Information and Demographics iCRFs should be completed. Three months after Day 0, or the admission date (inpatient or outpatient), the system expects for the Diagnosis and Staging iCRFs to be completed. Another 3 months later, or 6 months after Day 0, the system expects the Treatment form to be completed. After 6 more months, or 12 months after Day 0, the system expects the first Follow-up form to be completed, with the remaining follow-up forms to be completed yearly after. In the case of relapse or refractory disease that happened within the first year of treatment, this information is to be recorded in the first follow-up form, regardless of when within that year the relapse or refractory disease was confirmed.

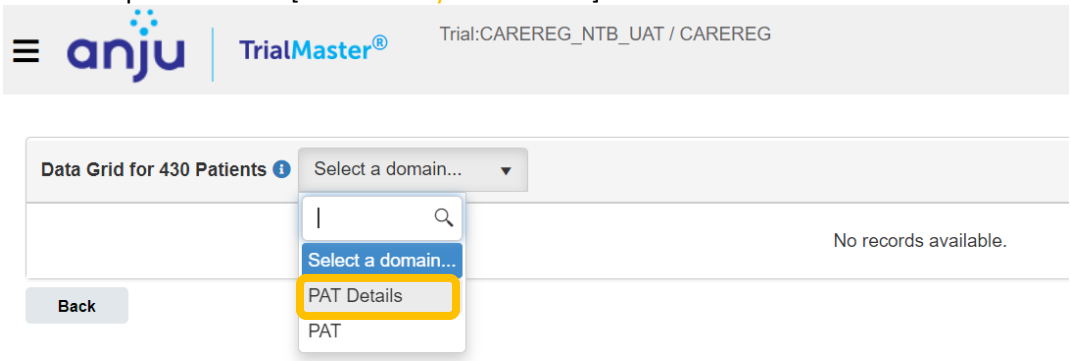
Appendix B. Helpful SJCARES Cancer Registry Platform Functionality

Searching for patients by name:

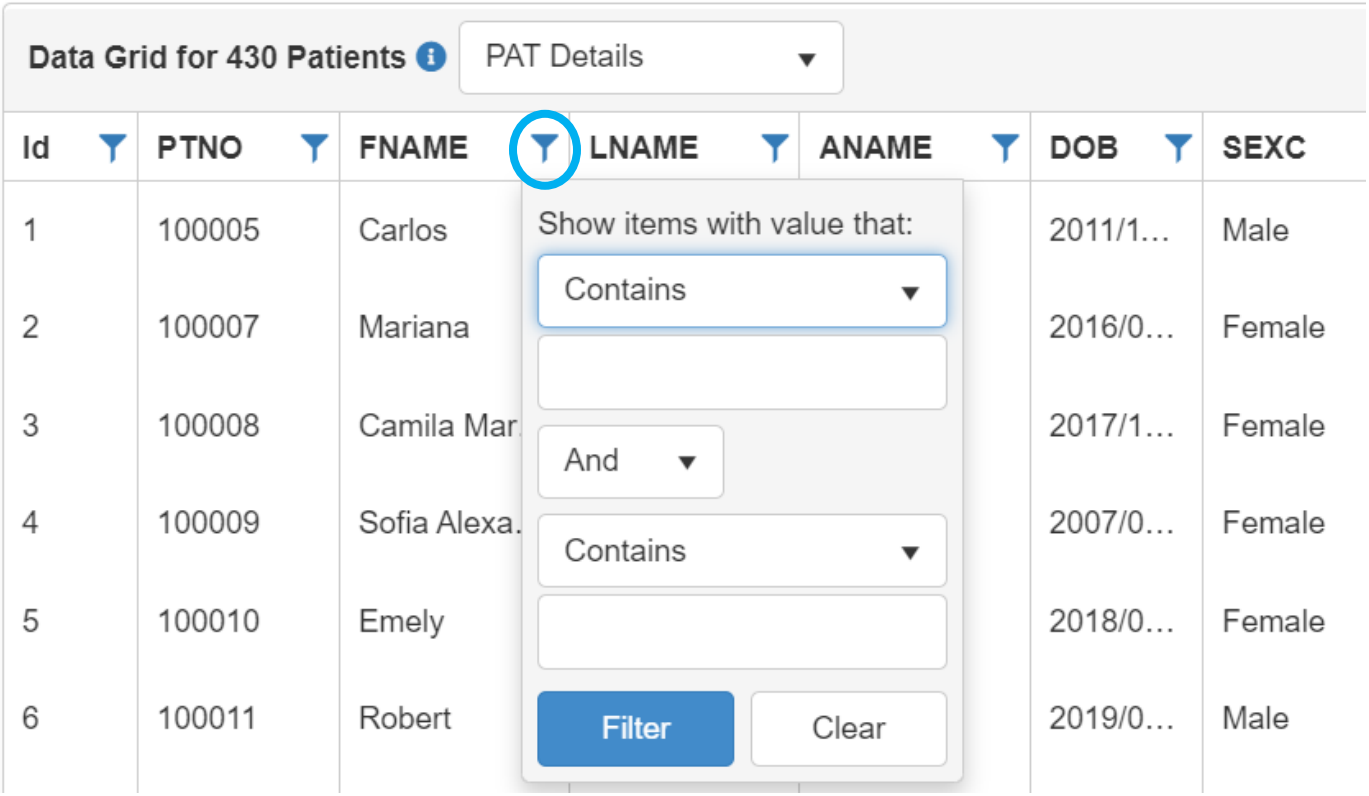
1) Go to the “Patients” list then check the box next to “Patient Caption” [circled in red] to select all and then click on the button marked “Data Grid” [outlined in green]



2) Click on “PAT Details” in the dropdown menu [outlined in yellow below]

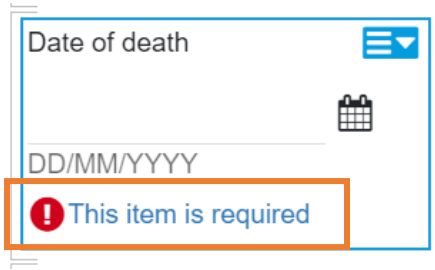


3) And then search for patients by name by filtering… [Filter by first name circled in blue below]

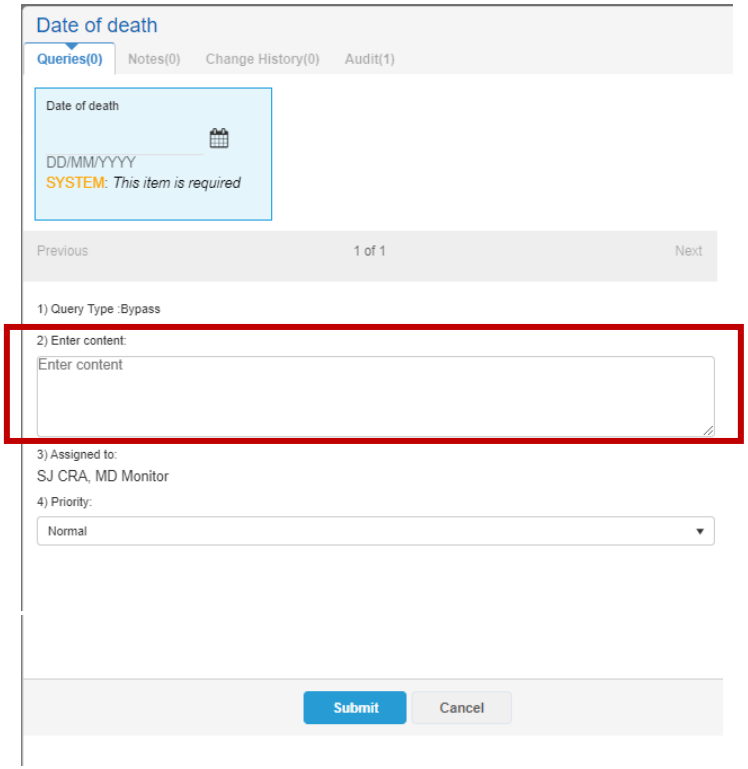


Bypass:

1) Locate the “This item is required” message underneath the data field that you would like to bypass:



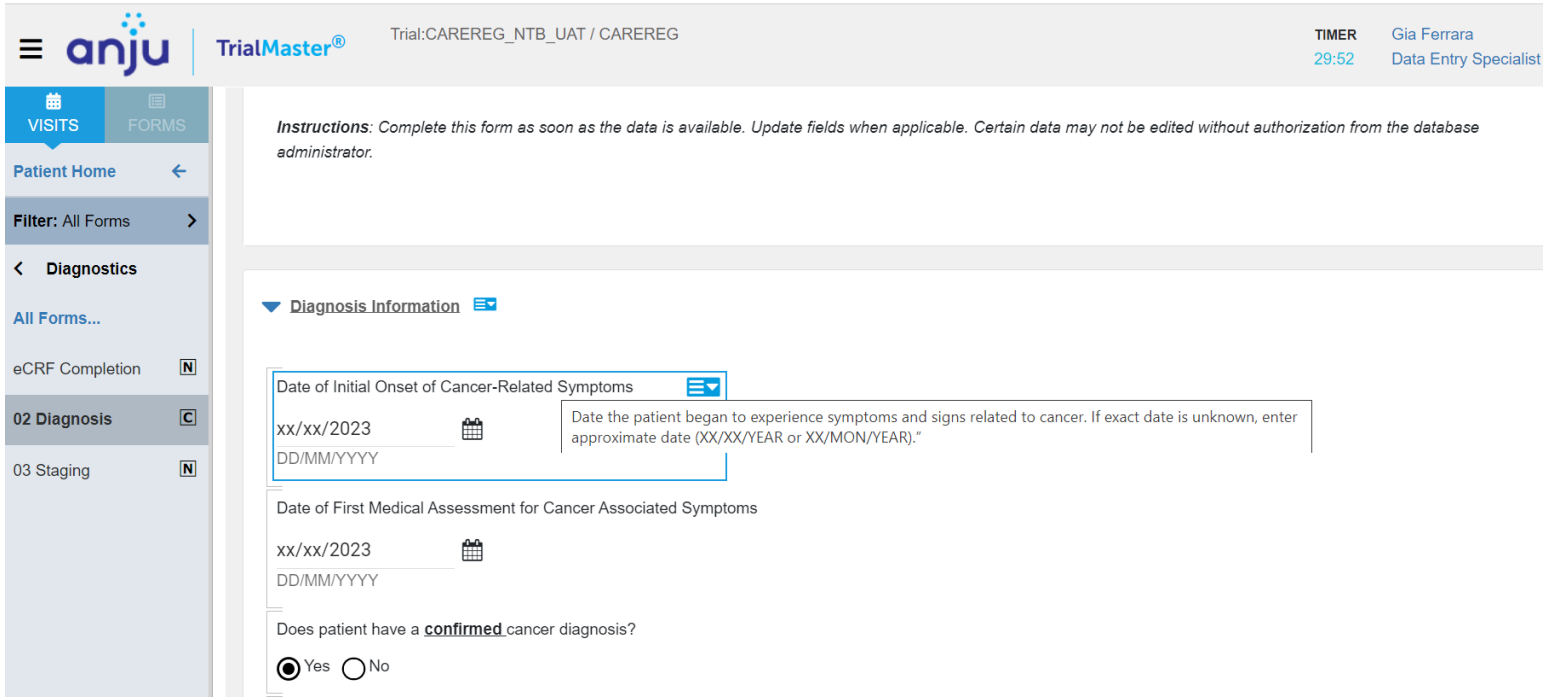
2) Click on the “This item is required” message [outlined in orange above]
   a. Doing this will open a Bypass Query window:



3) Enter in your notes and reasoning behind submitting the Bypass note for the corresponding data field in the “Enter content” box [outlined in red above].
4) Press the blue “Submit” button
5) Finish completing the form and save the form as Complete

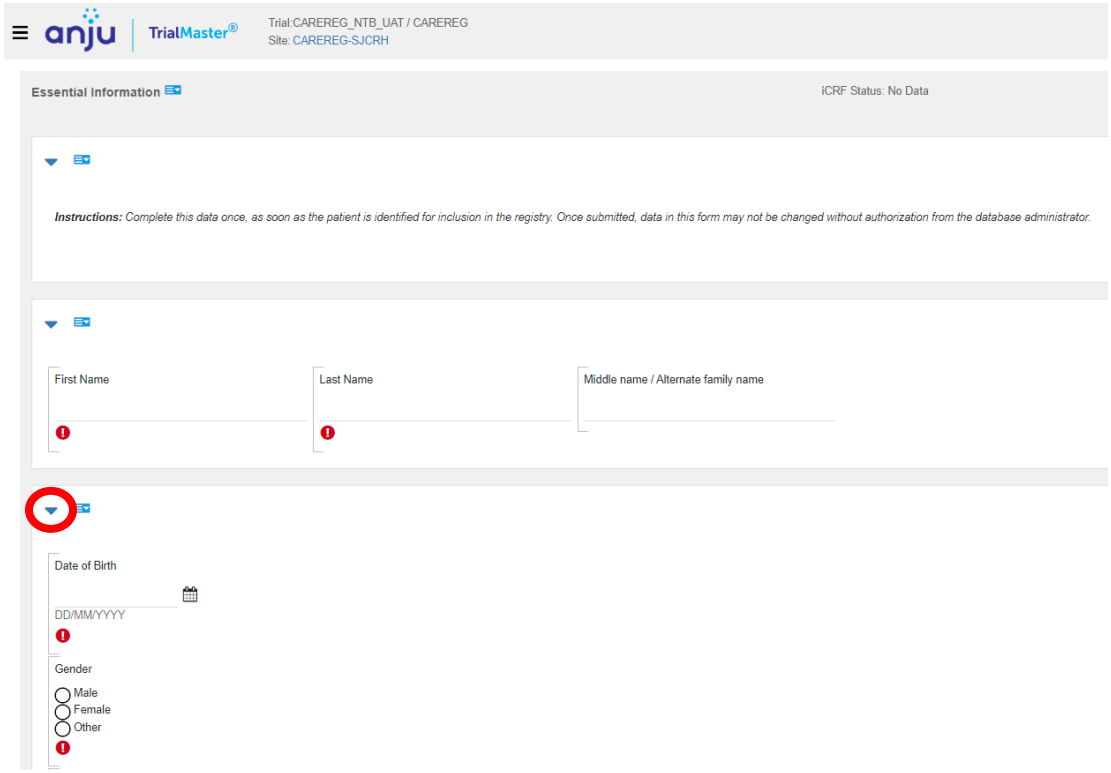
Appendix C. Helpful Hints/FAQ

- **Hover over the titles of the data elements on the iCRFs to get clear, concise definitions for each element. Example:**

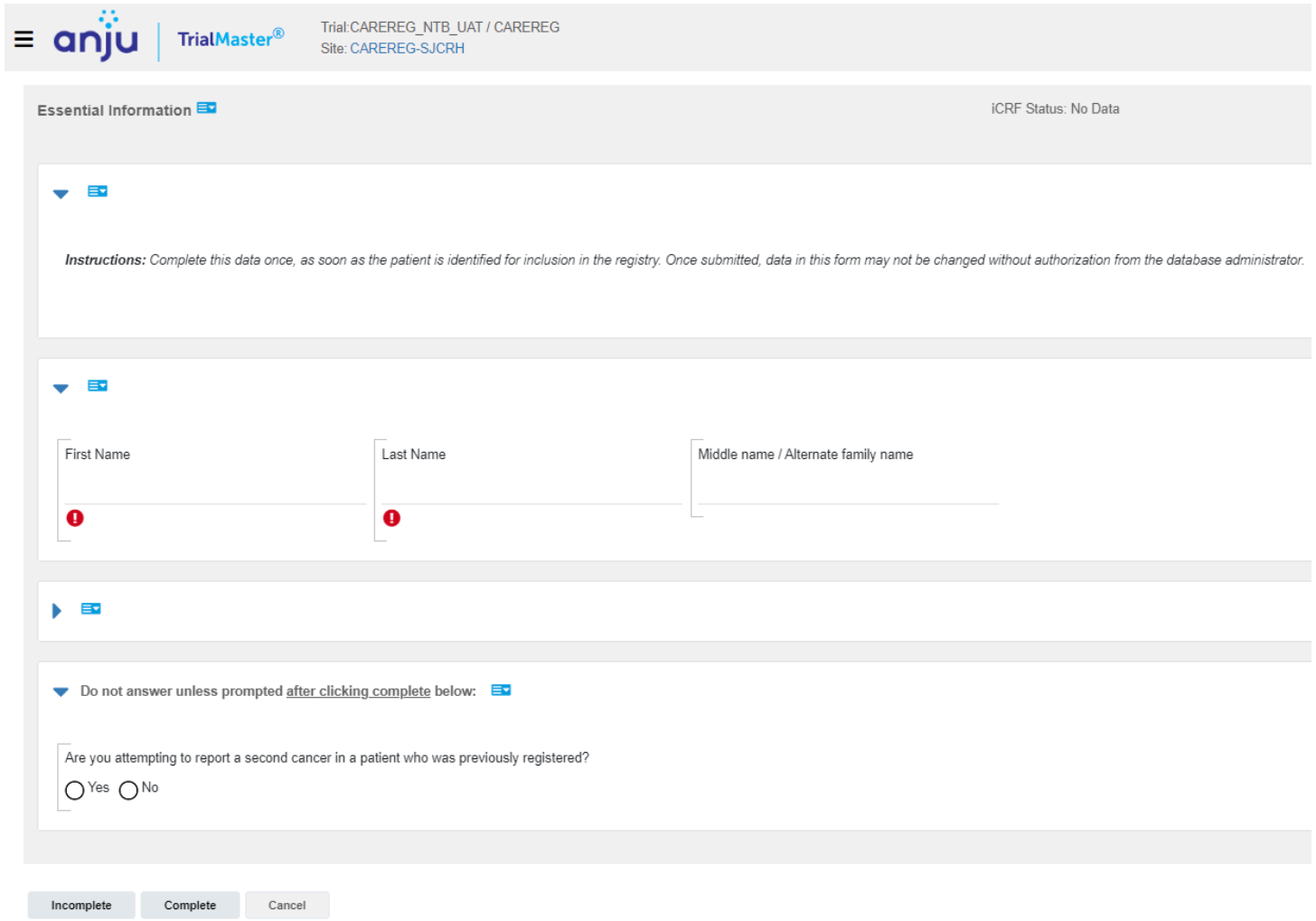


- **What does the icon mean?**
  - The icon indicates that the data field is a required field. The iCRF cannot be submitted as "Complete" until all the required fields are filled.
- **What is the Comments box for?**
  - This is a free text box where data entry specialists can leave relevant notes about information being captured on the specific iCRFs. Do NOT include Protected Health Information (PHI) in the Comments box.
- **What happens if I cannot enter in all the required data at one time?**
  - When filling out the iCRF forms, if you do not have all the required information you can save the form as "Incomplete" and go back to fill in the missing fields when the information is available.

- **What does “Expected Date Value” mean?**
    - When entering dates, it is important to remember the acceptable formats for each specific data field.
    - The Expected Date Value format encompasses two-digit day, two-character Months, and four-digit year. Uncertain date formats (“XX/XX/YYYY” and “XX/MM/YYYY”) can only be used for two data fields: the Date of Initial Onset of Cancer Related Symptoms and Date of First Medical Assessment for Cancer Associated Symptoms. This format allows entry of general dates when the exact date is unknown. Examples include “XX/XX/2010” and “XX/02/2015.”
- **If you don’t want to scroll through all of the data sections, use the arrow to the left of the section title (circled in red) to collapse and expand the data fields.**
    - Expanded:



- Collapsed:



- **Do not put PHI in any of the free text, comments areas because SJG Cancer Registry team members can see this information.**
- **What happens to a patient after 5 years of Follow-up?**

  Data goes to a deidentified databank for survivorship analysis.

Appendix D. Class of Case

Schema to help with identifying how to register class of case for different patient scenarios.

Patient Status upon Arrival to Your Hospital	Place of Diagnosis	Place of Initial Treatment	Place of Chemotherapy	Place of Non-Chemotherapy Treatment		Class of Case
New diagnosis	Your hospital	No treatment yet	n/a	n/a	Analytic	(1) New case to center without diagnosis and without treatment
Diagnosis at other hospital	Other hospital	No treatment yet	n/a	n/a	Analytic	(2) New case to center with diagnosis but without treatment
Diagnosis and surgery at other hospital	Other hospital	Other hospital	n/a	Surgery at other hospital	Analytic	(3) New case to center with diagnosis and non-chemotherapy cancer treatment elsewhere
Diagnosis and chemotherapy at other hospital	Other hospital	Other hospital	Other hospital	n/a	Non-analytic	(4) New case to center with diagnosis and chemotherapy cancer treatment elsewhere
Diagnosis and surgery, chemotherapy at other hospital	Other hospital	Other hospital	Other hospital	n/a	Non-analytic	(4) New case to center with diagnosis and chemotherapy cancer treatment elsewhere
Diagnosis at other hospital; cancer went into remission 11 months ago	Other hospital	Other hospital	Other hospital	n/a	Non-analytic	(5) New relapse or refractory disease case to center

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