



Oncology EHR Functional Requirements – High Level and User Specific

ID	Priority 1 = essential 2 = desired 3=eventually	Element/Functionality
1		<p>Plan for Course of Treatment</p> <ul style="list-style-type: none"> - drop down menu to select, neoadjuvant, adjuvant, curative, advanced - drop down menu to select, treatment 1, treatment 2, treatment 3, treatment 4, etc... <p><i>*Ability to make available an electronic copy (pdf for e-mail OR direct electronic transfer to another EHR) AND a printed copy of the summary plan for patient and other clinical providers</i></p>
1.1		DEMOGRAPHICS
1.1.1	1	Patient Demographics <ul style="list-style-type: none"> • Name, DOB, MRN • Contact information • Race and ethnicity • Language preference (optional field)
1.1.2	1	Treating physicians and their sub specialty area/Primary physicians <ul style="list-style-type: none"> • Name, Sub-specialty, Address, Phone, Fax
1.2		DIAGNOSIS
1.2.1	1	Primary Cancer Diagnosis (ICD-9, ICD-10, or other more clinically relevant system)
1.2.2	1	Pathology: (menu could be driven by disease) <ul style="list-style-type: none"> • Site • Histology/pathology • Biomarkers (ER, HER2, c-Kit etc) • Molecular markers (bcr+ etc) • Chromosomal markers
1.2.3	1	Primary Staging <ul style="list-style-type: none"> • AJCC for relevant diagnoses • Tumor registry staging system for non-AJCC diagnoses
1.2.4	1	Metastatic sites (if applicable)
1.2.5	1	Pathologic features of metastatic site (e.g. transformed lymphoma or ER neg breast ca)
1.2.6	1	List of co-morbid conditions which should be organ based choices
1.3		PRIOR TREATMENT
1.3.1	1	Prior Cancer Surgery (type/date)
1.3.2	1	Prior Chemotherapy/biotherapy regimens (table format with Regimen, Dates, Best response, Reason for discontinuation) – to feed in from flow sheet
1.3.3	1	Prior Radiation Therapy (site/date)
1.4		CURRENT PLAN



1.4.1	1	Intent/goals of therapy (adjuvant, neoadjuvant, advanced /palliative)
1.4.2	1	Performance status (including Karnofsky, etc...)
1.4.3	1	Sites of disease being monitored <ul style="list-style-type: none"> • Add choices of adjuvant (n/a), measurable, evaluable • List of indicator lesions/sites
1.4.4	1	Human body graphic (front and back) for recording sites of disease
1.4.5	1	Chemotherapy/biotherapy regimen planned
1.4.6	1	Clinical trial – protocol number
1.4.7	2	Link to clinical trial protocol document
1.4.8	1	Height, Weight, Body surface area (BSA) and starting doses (per m2, kg, flat)
1.4.9	1	Duration of treatment and number of planned cycles
1.4.10	1	Significant potential toxicities associated with planned treatment
1.4.11	1	Radiation Therapy planned
1.4.12	1	Surgery Planned
1.4.13	1	Pain assessment
1.4.14	1	Palliative care/hospice plan
1.4.15	1	Ability to make available an electronic copy (pdf for e-mail OR direct electronic transfer to another EHR) or a printed copy of the treatment plan Include treating MD and contact information, perhaps as a header or at the signature line
2.		<p>Summary of Course of Treatment <i>(longitudinal treatment/disease tracking tool w/each course of therapy, broken out: Neoadjuvant, Adjuvant; etc... that builds through time; accumulative)</i></p> <p><i>*Ability to make available an electronic copy (pdf for e-mail OR direct electronic transfer to another EHR) AND a printed copy of the summary plan for patient and other clinical providers</i></p>
2.1		DEMOGRAPHICS
2.1.1	1	Patient demographics <ul style="list-style-type: none"> • Name, DOB, MRN • Contact information • Race and ethnicity • Language preference (optional)
2.1.2	1	Referring/Primary physicians <ul style="list-style-type: none"> • Name, Sub-specialty, Address, Phone, Fax
2.2		DIAGNOSIS
2.2.1	1	Primary Cancer Diagnosis (ICD-9, ICD-10, or other more clinically relevant



		system)
2.2.2	1	Pathology: (menu could be driven by disease) <ul style="list-style-type: none"> • Site • Histology/pathology • Biomarkers (ER, HER2, c-Kit etc) • Molecular markers (bcr+ etc) • Chromosomal markers
2.2.3	1	Primary Staging <ul style="list-style-type: none"> • AJCC for relevant diagnoses • Tumor registry staging system for non-AJCC diagnoses
2.2.4	1	Metastatic sites (if applicable)
2.2.5	1	Pathology of metastatic site (e.g. transformed lymphoma or ER neg breast ca)
2.2.6	1	List of co-morbid conditions which should be organ based choices
2.3.		PRIOR TREATMENT
2.3.1	1	Prior Cancer Surgery (type/date)
2.3.2	1	Prior Chemotherapy/biotherapy regimens – (table format with Regimen, Dates, Best response, Reason for discontinuation)
2.3.3	1	Prior Radiation Therapy (site/date)
2.4.4		CURRENT TREATMENT
2.4.5	1	Intent/goals of therapy – (adjuvant, neoadjuvant, advanced /palliative)
2.4.6	1	Chemotherapy/biotherapy delivered – intravenous and oral <ul style="list-style-type: none"> • Protocol # (if applicable) • Height, weight, BSA • Dose/m2(kg), treatment dose • Number of cycles planned and administered <ul style="list-style-type: none"> • Duration (date of first and last dose) • Extent of dose reduction and reason for dose reduction-patient preference, declining PS, toxicity(neutropenic fever requiring hospitalization, specific toxicity reason) • Response to treatment
2.4.7	1	Sites of disease monitored- adjuvant(n/a), measurable/evaluable
2.4.8	1	Human body graphic (front and back) for recording sites of disease
2.4.9	1	Reason treatment stopped (choices: completed course, complete response, progression of disease, toxicity)
2.4.10	1	Major toxicities experienced (CTCAE list)
2.4.11	1	Hospitalization required for toxicity

2.4.12	1	Cancer surgery performed (type/date)
2.4.13	1	Radiation therapy (Date (mm/yy), Field, Response)
2.4.14	1	Disease status at completion of treatment (NED, CR, PR, MR, POD)
2.4.15	1	Performance status at completion of treatment (including Karnofsky, etc...)
2.4.16	1	Pain status during and at end of treatment
2.4.17	1	Palliative care/hospice plan
2.5.		FOLLOW-UP CARE
2.5.1	1	Practitioner(s) who will conduct follow up care with the patient: name, sub-specialty, address, phone, fax
2.5.2	1	Tasks to be followed up, complete with symptom management and disease surveillance (such as colonoscopy in 1 year by GI; CT Scan in 1 year by medical oncologist)
2.5.3	1	Calendar of follow up events, including <ul style="list-style-type: none"> • Further therapy needed • Followup frequency • Testing & time frame
2.5.4	1	Signature line with treating physician's contact information
3.		<i>Oncology-Specific Documentation</i>
3.1	1	Flow Sheets: preferably configurable by site to include the following sections <ul style="list-style-type: none"> • Treatment regimen summary table <ul style="list-style-type: none"> ○ regimen ○ start and stop date ○ response • Ongoing treatment (configurable for disease specificity) <ul style="list-style-type: none"> ○ Chemotherapy treatment (intravenous and oral) ○ Other medications ○ Transfusions ○ Radiation ○ Physical finding (including performance status) ○ Tumor measurements ○ Radiographic (indicate a date and the assessment as to stable disease, POD or response) – should have a link to the actual image in the PACS ○ Lab values - with associated labs normal ranges and tumor markers ○ Toxicity - to document the adverse events experienced from drop down list of CTCAE



3.2	1	Medical Record: <ul style="list-style-type: none"> • Date of diagnosis • Initial Staging • Current stage • Physical findings to include- including tumor measurements and performance status • Relevant procedures notes: admit note, operative notes, procedure notes, chemotherapy record, discharge notes these are part of general medical record • Pain assessment • Graphic, photos and sketch handling • Radiation reports • Pathology reports • Consents • End of life documentation – scanned documents to include: DNR, etc...
3.3	1	Cause of Death/Date of Death <ul style="list-style-type: none"> • Date and reason list • Autopsy – date and key findings
3.4.		Decision Support Tools:
3.4.1	1	Staging guidelines
3.4.2	1	CTCAE toxicity guidelines
3.4.3	1	NCCN guidelines, regimens & compendium
3.4.4	3	Chemotherapy/biotherapy drug guidelines for individual drugs
3.4.5	1	ASCO guidelines and tools
3.4.6	1	Pain management – scales, guidelines, resources
3.4.7	1	Anti-emetic guidelines
3.4.8	1	Ability to incorporate institutional specific SOP’s/guidelines/workflows
3.4.9	1	Template based tools for encounters and visits
3.4.10	2	Analysis of the feasibility of an institution/practice to meet a clinical trials’ accrual goals – system generated report of a sites patient’s demographics profile for matching eligibility requirements for a given trial
3.4.11	1	Clinical trial matching – system generated notification when a patient is eligible for a trial and an abbreviated summary of the trial to share with the patient
3.5		Education Record:
3.5.1	1	<ul style="list-style-type: none"> • Education checklist - documentation of what education was given by whom and when, citing the materials given to the patient and if an interpreter was present
3.5.2	1	Patient education resources – should be able to download and print national



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		teaching pamphlets/handouts, as well as internally authored pamphlets/handouts and templates
4.		<i>Oncology Specific EHR Functionality</i>
4.1.		Chemotherapy/Drug Management –
4.1.1.		Chemotherapy ordering system
4.1.1.2	1	<ul style="list-style-type: none"> ability to order electronically
4.1.1.3	1	<ul style="list-style-type: none"> to interface with pharmacy system
4.1.1.4	1	<ul style="list-style-type: none"> to interface with electronic medication administration record
4.1.1.5	1	<ul style="list-style-type: none"> ability to choose from predetermined regimen order sets of standard regimens or study protocols (configurable per institution)
4.1.1.6	2	<ul style="list-style-type: none"> electronic link to protocol from the order
4.1.1.7	1	<ul style="list-style-type: none"> ability to have dates fill in automatically for multiday/week therapy
4.1.1.8	1	<ul style="list-style-type: none"> ability to reorder from prior cycle
4.1.1.9	1	<ul style="list-style-type: none"> ability to modify orders/doses
4.1.1.10	1	<ul style="list-style-type: none"> document treatment parameters on order
4.1.1.11	1	<ul style="list-style-type: none"> signing off electronically on each cycle
4.1.1.12	1	<ul style="list-style-type: none"> verify orders electronically by nursing and pharmacy after MD/NP signs
4.1.1.13	1	<ul style="list-style-type: none"> Ability to use the previous height/weight or apply the new height/weight
4.1.1.14	1	<ul style="list-style-type: none"> Chemotherapy order sets - including NCCN guidelines and order sets, internal order sets, plus access to a library of standards based regimens and standards based protocols

4.1.2	1	<p>Chemotherapy dosing functions</p> <ul style="list-style-type: none"> • Calculators built into electronic ordering system • Ability to set different dose bases (AUC, Cockcroft Gault etc) based on regimen. • Ability to cap doses based on regimen • Based on height, weight, creatinine clearance (AUC), creatinine, etc... from a selected list of options configurable at an institutional level • Ability for system to pull height, weight, creatinine from central EHR for dose calculations • Ability to set parameters for lab results (for example a system can be configured to not use a Cr level below 0.7 but instead require a level of 0.7 or higher be used for AUC calculations) • Dose rounding rules incorporated into calculators • Ability to document total daily dose to be administered
4.1.3	1	<p>Safety guardrails within electronic ordering</p> <ul style="list-style-type: none"> • Maximum dose ranges per drug • Inappropriate routes of administration locked out per drug • Allergy alert/checking • Drug/drug interaction checking • Height/weight change alert/checking • Lifetime cumulative chemotherapy dose tracking • Height weight flow sheets for Pediatric patients
4.1.4	1	<p>Supportive medication management/order sets</p> <ul style="list-style-type: none"> • anti-emetics, hydration • growth factors • supportive meds • hypersensitivity reaction guideline
4.1.5	1	Verbal orders can only be used for cancelling a treatment, but then must have follow-up by electronic signature
4.1.6	1	When changing treatment, system must request a reason from a drop down list of defined reasons.
4.1.7	1	If medication dose changes once treatment regimen begins, systems must request a reason from a drop down list of defined reasons
4.1.8	1	Drug/laboratory alert – from lab results that impact drug administration
4.1.9	1	Extravasations records and guidelines
4.1.10	1	Electronic chemo administration record that documents dose etc AND site of

		infusion (which hand, mediport etc)
4.1.11	1	Hazardous spill record and guidelines
4.1.12	1	Chemotherapy-specific drug labeling (configurable)
4.1.13	1	Medication list, current and historical including over the counter or complementary medicine
4.1.14	1	Drug mixing instructions, solubility, stability, storage/expiration
4.1.15	1	ePrescription
4.2		Oncology-specific Billing Charge Capture/ Inventory Control -
4.2.1	1	<ul style="list-style-type: none"> • must be able to interface with an existing billing management system and an inventory control system:
4.2.2	1	<ul style="list-style-type: none"> • Track drug/supply chain of event (inventory received, source, dose dispensed, lot #, dose discarded and why, waste record, expiration record/notification, spill record and documentation) <i>Note</i>, these pharmacy functionalities could be handled outside of the EHR by the pharmacy management system.
4.2.3	1	<ul style="list-style-type: none"> • Ability to track the source of the drug – pharma, clinical trial, vendor (customizable) oncology specific but should be part of the pharmacy system <i>Note</i>, these pharmacy functionalities could be handled outside of the EHR by the pharmacy management system.
4.2.4	1	<ul style="list-style-type: none"> • Chemotherapy coding (J-codes) and reimbursement management should be part of a pharmacy system
4.2.5	1	<ul style="list-style-type: none"> • Oncology specific procedure codes and drug administration billing codes (time dependent) for total record of charges
4.2.6	1	<ul style="list-style-type: none"> • Mechanism for insurance pre-authorization – ability to electronically submit notification to billing office and billing system OR generate a report that can be taken to billing...configurable based on organizations needs not oncology specific
4.2.7	1	<ul style="list-style-type: none"> • Billing office alert for all drugs/treatments to approve/authorize.
4.2.8	1	<ul style="list-style-type: none"> • Access to approved drug compendia
4.3.		Calendar/Scheduler: will have alerts and pop-ups to remind caregiver of scheduled treatments, etc...
4.3.1	1	<ul style="list-style-type: none"> • Ability to schedule regimens/full course of care, to include: <ul style="list-style-type: none"> ○ Physician visits ○ Education/training ○ Lab/radiology ○ Infusion ○ Injections
4.3.2	1	<ul style="list-style-type: none"> • Ability to update the calendar easily and push dates accordingly
4.3.3	1	<ul style="list-style-type: none"> • Chemo chair scheduling
4.3.4	1	<ul style="list-style-type: none"> • Ability to print off calendar of treatments, lab and radiology

		appointments, physician appointments to give to patient
4.3.5	1	<ul style="list-style-type: none"> Regimen specific calendar that can be printed off for the patient as well that includes the drugs being given/taken, lab appointments, radiology appointments, physician appointments, side effects, etc...
4.3.6	1	<ul style="list-style-type: none"> Calendar for patients that records the days oral medications should be taken and time interval with space for them to record actual time taken and any side effects experienced: <ul style="list-style-type: none"> Printable calendar that can then be scanned into the patients record when completed Through a patient portal, the ability for patients to provide this information electronically to their own record
4.4.		Clinical Trials and Research Support - integration of, access to and/or support for research and clinical trials tools including:
4.4.1	1	<ul style="list-style-type: none"> Clinical trials and research tools (caBIG)
4.4.2	1	<ul style="list-style-type: none"> Investigational drug documentation with the ability to customize to meet the needs of each sponsors requirements – links to protocol
4.4.3	1	<ul style="list-style-type: none"> Clinical trial accrual monitoring and screening logic (NCCCP CT Screening and Accrual log captures all of this information...see attached) <ul style="list-style-type: none"> If patient accrued to a trial, which trial did they accrue to Was a clinical trial available to offer the patient If available, was the clinical trial offered, and if not why If participation was declined, why did they decline
4.4.4	2	<ul style="list-style-type: none"> Deductive Reasoning: notify organization that a trial did not exist for a population of patients (such as clinical trial options for elderly or for patient that have had cancer and are in post-treatment/cured phase)
4.4.5	2	Electronic NCI/FDA common CRF reporting capability
4.5	1	<p>End of Life Tools: ability to print templates for patient and ability to scan and save signed copies.</p> <ul style="list-style-type: none"> Health care proxies Living wills Power of attorney Do Not Resuscitate (DNR)
4.6	X	<p>Patient Portal:</p> <ul style="list-style-type: none"> Ability for patient to provide information to the provider electronically, such as: <ul style="list-style-type: none"> Performance status Pain control Quality of life Medication record Holistic/alternative therapies Access to the patient’s medical record

		<ul style="list-style-type: none"> • Access to lab/radiology results • Personal health record • Provide education pamphlets (links to NCI and ability to import organizations own teaching materials), template medication records, etc...
4.7	3	Bar-Coding/Labeling: <ul style="list-style-type: none"> • Radiofrequency identification (RFID) technology for patient identification to orders, drugs, treatments, etc... • Bar code labels for drugs/supplies • Bar code labels for lab/pathology samples
4.8	1	Reporting: Metrics, Utilization and Quality <ul style="list-style-type: none"> • Cost effectiveness • Cost of care related to a regimen (resource utilization) • Patterns of Care • Practice population analysis • Quality of life measurement • Disease surveillance • Timeliness of care measurement • Financial analysis and reporting, including utilization • Outcomes analysis tools • Customizable reports
4.9	1	Communication: <ul style="list-style-type: none"> • Ability to send a report, referral, treatment summary to other providers electronically AND/OR printed copy to mail • Interoperable with lab, radiology, hospital information management system, other clinical system considered mission critical • Ability to machine read written reports (pathology)
5.0		Interoperability, Security and Data Standards:
5.1	X	Interoperability – Health information exchange (HIE) with labs, imaging centers, etc.
5.2	X	Able to exchange clinical information with other information systems using standards that retain the available level of coding and structure, such as the HL7 Clinical Data Architecture.
5.3	X	Able to enter information once and have it auto-populate multiple fields, as indicated
5.4	X	Programmatic access to query/retrieve data from an external resource
5.5	X	Local vocabularies or publicly accessible controlled vocabularies are used
5.6	X	Vocabularies must include term names that meet caBIG VCDE workspace guidelines.



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5.7	X	Data element descriptions are maintained with sufficient definitional depth to enable a subject matter expert to unambiguously interpret the contents of the resource without contacting the original investigator.
5.8	X	Data elements are built using controlled terminology
5.9	X	Metadata is stored and publicized in an electronic format that is separate from the resource that is being described
5.10	X	Diagrammatic representation of the information model is available in electronic format <u>XXXXXXXXXXXXXXXXXXXXXXXXXXXX</u> Data ownership- Storage- Ownership- Security- Risk management – risk identification; qualitative/quantitative analysis; response planning
5.11	X	Open database with query capabilities
6.		Compliance Safeguards
6.1	X	Privacy and Security safeguards in place
6.2	X	Disaster Recovery plan in place