



Kevin Hurley, MD  
Project Manager  
Clinical Oncology Requirements for the EHR (CORE)  
National Cancer Institute

October 16, 2009

Dear Dr. Hurley,

The American Society of Hematology (ASH) appreciates the opportunity to provide comment from hematologists, who treat both malignant and non-malignant hematologic disorders, regarding the plans of the National Cancer Institute (NCI) to promote clinical oncology requirements for Electronic Health Record (EHR) vendors. ASH agrees that this project is essential to ensure the value of the EHR for patients and practitioners to serve clinical care, research, quality assessment, and the financial underpinnings of hematology practice. The Society is grateful for the efforts of the NCI and other groups to provide leadership to this important work, and appreciate the efforts of the volunteer working groups who have made this possible.

ASH solicited comments from its Committee on Practice and Subcommittees on Quality of Care and Reimbursement members about this draft set of requirements, and this document reflects their responses.

In general, ASH agrees with the value, purpose and imperative to generate a consensus-driven, common requirements framework for oncology EHR applications. Several common themes emerged from the feedback ASH received from its network of practitioners.

First, although this set of requirements is directed towards management of conditions found in oncology practices, there was agreement that these requirements would be applicable to the practice of malignant hematology with minimal adaptation. Non-malignant hematology is less well encompassed by this set of requirements. However, many of the modules and much of the functionality and architecture that would be needed to support the requirements for an Oncology EHR would support, or could be reasonably adapted to support an EHR for non-malignant hematology consultations. In fact, ASH is very supportive of this concept, and would consider working with the NCI and other groups to develop such a requirements document modification. For example, a module that included transfusion ordering, tracking, adverse event reporting and other transfusion support tools would be important for a hematology-specific EHR. There are many other possible examples of modifications that could be adopted to support hematology.

Second, ASH members believed that the Oncology EHR requirements document should more explicitly describe requirements for patient education with a module that will use information entered into the EHR to generate complete and thorough diagnosis and treatment plan summaries that can be provided to patients and caregivers. These plan summaries, if well-developed with data standards, can be connected with application modules using emerging guidelines to generate patient-specific long-term follow-up education and management plans. This follows

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recommendations from a 2005 Institute of Medicine report “From Cancer Patient to Cancer Care Survivor: Lost in Transition” (<http://www.iom.edu/CMS/28312/4931/30869.aspx>, accessed October 1, 2009). To this end, ASH also recommends that EHRs be adaptable to readily incorporate emerging or revised clinical practice guidelines in a broad sense, as discussed in issue 3.4.3.

Third, there was general concern regarding the cost of implementing EHRs in the community practice environment, where the risk-benefit equation and economies of scale are quite different than in academic practice or large hospitals. Cost and time to implement an EHR can be substantial, especially when integration with legacy medical records, development of new work flow processes, and maintenance are added to the considerations. Some of the impact of these issues might be modified if the Oncology EHR module is integrated within a well-designed general medical EHR application that provides a solution encompassing all components of practice including scheduling, medication ordering, laboratory ordering and tracking, digital radiographic viewing, documentation and billing, and practice management. Although concerns about cost are not directly an issue of the requirements documentation process, cost may inform the process and should be a consideration of EHR providers.

Finally, the most crucial comment from the hematology community was to emphasize strongly the need for interoperability of EHR applications (section 5), and privacy and security (section 6). Current EHR applications largely exist to generate documentation that supports robust billing practices for reimbursement. While this is obviously an important function of an EHR, and is one major concern of health care institutions, the oncology and hematology community look to the NCI and others to strongly promote the need for future generations of EHR applications to adopt and maintain data standards to promote interoperability. Interoperability will leverage the applicability of the medical records obtained through EHR with regard to clinical trial and regulatory reporting (e.g. FDA, Stem Cell Therapeutics and Research Act of 2005, and others), required data and outcomes reporting for NIH grant recipients, biovigilance and pharmacosurveillance, generation of robust patient education materials, clinical outcomes reporting for local, state and federal quality assurance and patient safety initiatives, communication between health care professionals about patients (transfers, handoffs), and research. Interoperability will dramatically leverage the value of these systems for all stakeholders, particularly clinicians. ASH strongly believes that interoperable data standards, including those within the caDSR/caBIG, HL7, should be a requirement of any EHR system in this environment. The draft document circulated for review does not list a priority for this requirement, which our reviewers believe is an oversight. Without the use of data standards and advanced planning for interoperability, much of the usefulness and functionality of EHRs will not be achieved. Market forces alone are not strong enough to promote their adoption by the EHR vendors, hence the recommendation from ASH that these items be listed as a priority = 1 (essential). Without such a strong statement from this requirements process, a substantial opportunity will be lost. Consistent with this recommendation, ASH also urges that this requirements document include a statement strongly advocating for EHRs that generate non-proprietary, open source databases that use the data standards and support open source data query tools that will enhance interoperability.

Once again, ASH appreciates the obvious efforts of the stakeholder groups who participated in the development of these Oncology EHR requirements and the request for hematology feedback.

Please contact Carol Schwartz, Senior Manager of Policy & Practice at (202)292-0298 or [cschwartz@hematology.org](mailto:cschwartz@hematology.org) for additional discussion.

Sincerely,

A handwritten signature in black ink that reads "Nancy Berliner". The signature is written in a cursive, flowing style.

Nancy Berliner, MD



## Oncology EHR Functional Requirements – High Level and User Specific

ID	Priority 1 = essential 2 = desired 3=eventually	Element/Functionality
1		<p><b>Plan for Course of Treatment</b></p> <ul style="list-style-type: none"> <li>- drop down menu to select, neoadjuvant, adjuvant, curative, advanced</li> <li>- drop down menu to select, treatment 1, treatment 2, treatment 3, treatment 4, etc...</li> </ul> <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		<b>DEMOGRAPHICS</b>
1.1.1	1	Patient Demographics <ul style="list-style-type: none"> <li>• Name, DOB, MRN</li> <li>• Contact information</li> <li>• Race and ethnicity</li> <li>• Language preference (optional field)</li> </ul>
1.1.2	1	Treating physicians and their sub specialty area/Primary physicians <ul style="list-style-type: none"> <li>• Name, Sub-specialty, Address, Phone, Fax</li> </ul>
1.2		<b>DIAGNOSIS</b>
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"> <li>• Site</li> <li>• Histology/pathology</li> <li>• Biomarkers (ER, HER2, c-Kit etc)</li> <li>• Molecular markers (bcr+ etc)</li> <li>• Chromosomal markers</li> </ul>
1.2.3	1	Primary Staging <ul style="list-style-type: none"> <li>• AJCC for relevant diagnoses</li> <li>• Tumor registry staging system for non-AJCC diagnoses</li> </ul>
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		<b>PRIOR TREATMENT</b>
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		<b>CURRENT PLAN</b>



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"> <li>• Add choices of adjuvant (n/a), measurable, evaluable</li> <li>• List of indicator lesions/sites</li> </ul>
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.		<b>Summary of Course of Treatment</b> <i>( longitudinal treatment/disease tracking tool w/each course of therapy, broken out: Neoadjuvant, Adjuvant; etc... that builds through time; accumulative)</i>  <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>
2.1		<b>DEMOGRAPHICS</b>
2.1.1	1	Patient demographics <ul style="list-style-type: none"> <li>• Name, DOB, MRN</li> <li>• Contact information</li> <li>• Race and ethnicity</li> <li>• Language preference (optional)</li> </ul>
2.1.2	1	Referring/Primary physicians <ul style="list-style-type: none"> <li>• Name, Sub-specialty, Address, Phone, Fax</li> </ul>
2.2		<b>DIAGNOSIS</b>
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"> <li>• Site</li> <li>• Histology/pathology</li> <li>• Biomarkers (ER, HER2, c-Kit etc)</li> <li>• Molecular markers (bcr+ etc)</li> <li>• Chromosomal markers</li> </ul>
2.2.3	1	Primary Staging <ul style="list-style-type: none"> <li>• AJCC for relevant diagnoses</li> <li>• Tumor registry staging system for non-AJCC diagnoses</li> </ul>
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.		<b>PRIOR TREATMENT</b>
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		<b>CURRENT TREATMENT</b>
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"> <li>• Protocol # (if applicable)</li> <li>• Height, weight, BSA</li> <li>• Dose/m2(kg), treatment dose</li> <li>• Number of cycles planned and administered <ul style="list-style-type: none"> <li>• Duration (date of first and last dose)</li> <li>• Extent of dose reduction and reason for dose reduction-patient preference, declining PS, toxicity(neutropenic fever requiring hospitalization, specific toxicity reason)</li> </ul> </li> <li>• Response to treatment</li> </ul>
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.		<b>FOLLOW-UP CARE</b>
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"> <li>• Further therapy needed</li> <li>• Followup frequency</li> <li>• Testing &amp; time frame</li> </ul>
2.5.4	1	Signature line with treating physician's contact information
3.		<b><i>Oncology-Specific Documentation</i></b>
3.1	1	<b>Flow Sheets: preferably configurable by site</b> to include the following sections <ul style="list-style-type: none"> <li>• Treatment regimen summary table <ul style="list-style-type: none"> <li>○ regimen</li> <li>○ start and stop date</li> <li>○ response</li> </ul> </li> <li>• Ongoing treatment (configurable for disease specificity) <ul style="list-style-type: none"> <li>○ Chemotherapy treatment (intravenous and oral)</li> <li>○ Other medications</li> <li>○ Transfusions</li> <li>○ Radiation</li> <li>○ Physical finding (including performance status)</li> <li>○ Tumor measurements</li> <li>○ 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</li> <li>○ Lab values - with associated labs normal ranges and tumor markers</li> <li>○ Toxicity - to document the adverse events experienced from drop down list of CTCAE</li> </ul> </li> </ul>

3.2	1	<b>Medical Record:</b> <ul style="list-style-type: none"> <li>• Date of diagnosis</li> <li>• Initial Staging</li> <li>• Current stage</li> <li>• Physical findings to include- including tumor measurements and performance status</li> <li>• Relevant procedures notes: admit note, operative notes, procedure notes, chemotherapy record, discharge notes these are part of general medical record</li> <li>• Pain assessment</li> <li>• Graphic, photos and sketch handling</li> <li>• Radiation reports</li> <li>• Pathology reports</li> <li>• Consents</li> <li>• End of life documentation – scanned documents to include: DNR, etc...</li> </ul>
3.3	1	<b>Cause of Death/Date of Death</b> <ul style="list-style-type: none"> <li>• Date and reason list</li> <li>• Autopsy – date and key findings</li> </ul>
3.4.		<b>Decision Support Tools:</b>
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		<b>Education Record:</b>
3.5.1	1	<ul style="list-style-type: none"> <li>• 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</li> </ul>
3.5.2	1	Patient education resources – should be able to download and print national



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

4.1.2	1	<p><b>Chemotherapy dosing functions</b></p> <ul style="list-style-type: none"> <li>• Calculators built into electronic ordering system</li> <li>• Ability to set different dose bases (AUC, Cockcroft Gault etc) based on regimen.</li> <li>• Ability to cap doses based on regimen</li> <li>• Based on height, weight, creatinine clearance (AUC), creatinine, etc... from a selected list of options configurable at an institutional level</li> <li>• Ability for system to pull height, weight, creatinine from central EHR for dose calculations</li> <li>• 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)</li> <li>• Dose rounding rules incorporated into calculators</li> <li>• Ability to document total daily dose to be administered</li> </ul>
4.1.3	1	<p><b>Safety guardrails within electronic ordering</b></p> <ul style="list-style-type: none"> <li>• Maximum dose ranges per drug</li> <li>• Inappropriate routes of administration locked out per drug</li> <li>• Allergy alert/checking</li> <li>• Drug/drug interaction checking</li> <li>• Height/weight change alert/checking</li> <li>• Lifetime cumulative chemotherapy dose tracking</li> <li>• Height weight flow sheets for Pediatric patients</li> </ul>
4.1.4	1	<p><b>Supportive medication management/order sets</b></p> <ul style="list-style-type: none"> <li>• anti-emetics, hydration</li> <li>• growth factors</li> <li>• supportive meds</li> <li>• hypersensitivity reaction guideline</li> </ul>
4.1.5	1	<p>Verbal orders can only be used for cancelling a treatment, but then must have follow-up by electronic signature</p>
4.1.6	1	<p>When changing treatment, system must request a reason from a drop down list of defined reasons.</p>
4.1.7	1	<p>If medication dose changes once treatment regimen begins, systems must request a reason from a drop down list of defined reasons</p>
4.1.8	1	<p>Drug/laboratory alert – from lab results that impact drug administration</p>
4.1.9	1	<p>Extravasations records and guidelines</p>
4.1.10	1	<p>Electronic chemo administration record that documents dose etc AND site of</p>

		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		<b>Oncology-specific Billing Charge Capture/ Inventory Control -</b>
4.2.1	1	<ul style="list-style-type: none"> <li>• must be able to interface with an existing billing management system and an inventory control system:</li> </ul>
4.2.2	1	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
4.2.3	1	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
4.2.4	1	<ul style="list-style-type: none"> <li>• Chemotherapy coding (J-codes) and reimbursement management should be part of a pharmacy system</li> </ul>
4.2.5	1	<ul style="list-style-type: none"> <li>• Oncology specific procedure codes and drug administration billing codes (time dependent) for total record of charges</li> </ul>
4.2.6	1	<ul style="list-style-type: none"> <li>• 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</li> </ul>
4.2.7	1	<ul style="list-style-type: none"> <li>• Billing office alert for all drugs/treatments to approve/authorize.</li> </ul>
4.2.8	1	<ul style="list-style-type: none"> <li>• Access to approved drug compendia</li> </ul>
4.3.		<b>Calendar/Scheduler:</b> will have alerts and pop-ups to remind caregiver of scheduled treatments, etc...
4.3.1	1	<ul style="list-style-type: none"> <li>• Ability to schedule regimens/full course of care, to include: <ul style="list-style-type: none"> <li>○ Physician visits</li> <li>○ Education/training</li> <li>○ Lab/radiology</li> <li>○ Infusion</li> <li>○ Injections</li> </ul> </li> </ul>
4.3.2	1	<ul style="list-style-type: none"> <li>• Ability to update the calendar easily and push dates accordingly</li> </ul>
4.3.3	1	<ul style="list-style-type: none"> <li>• Chemo chair scheduling</li> </ul>
4.3.4	1	<ul style="list-style-type: none"> <li>• Ability to print off calendar of treatments, lab and radiology</li> </ul>

		appointments, physician appointments to give to patient
4.3.5	1	<ul style="list-style-type: none"> <li>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...</li> </ul>
4.3.6	1	<ul style="list-style-type: none"> <li>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"> <li>Printable calendar that can then be scanned into the patients record when completed</li> <li>Through a patient portal, the ability for patients to provide this information electronically to their own record</li> </ul> </li> </ul>
4.4.		<b>Clinical Trials and Research Support</b> - integration of, access to and/or support for research and clinical trials tools including:
4.4.1	1	<ul style="list-style-type: none"> <li>Clinical trials and research tools (caBIG)</li> </ul>
4.4.2	1	<ul style="list-style-type: none"> <li>Investigational drug documentation with the ability to customize to meet the needs of each sponsors requirements – links to protocol</li> </ul>
4.4.3	1	<ul style="list-style-type: none"> <li>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"> <li>If patient accrued to a trial, which trial did they accrue to</li> <li>Was a clinical trial available to offer the patient</li> <li>If available, was the clinical trial offered, and if not why</li> <li>If participation was declined, why did they decline</li> </ul> </li> </ul>
4.4.4	2	<ul style="list-style-type: none"> <li>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)</li> </ul>
4.4.5	2	Electronic NCI/FDA common CRF reporting capability
4.5	1	<p><b>End of Life Tools:</b> ability to print templates for patient and ability to scan and save signed copies.</p> <ul style="list-style-type: none"> <li>Health care proxies</li> <li>Living wills</li> <li>Power of attorney</li> <li>Do Not Resuscitate (DNR)</li> </ul>
4.6	X	<p><b>Patient Portal:</b></p> <ul style="list-style-type: none"> <li>Ability for patient to provide information to the provider electronically, such as: <ul style="list-style-type: none"> <li>Performance status</li> <li>Pain control</li> <li>Quality of life</li> <li>Medication record</li> <li>Holistic/alternative therapies</li> </ul> </li> <li>Access to the patient’s medical record</li> </ul>

		<ul style="list-style-type: none"> <li>• Access to lab/radiology results</li> <li>• Personal health record</li> <li>• Provide education pamphlets (links to NCI and ability to import organizations own teaching materials), template medication records, etc...</li> </ul>
4.7	3	<b>Bar-Coding/Labeling:</b> <ul style="list-style-type: none"> <li>• Radiofrequency identification (RFID) technology for patient identification to orders, drugs, treatments, etc...</li> <li>• Bar code labels for drugs/supplies</li> <li>• Bar code labels for lab/pathology samples</li> </ul>
4.8	1	<b>Reporting: Metrics, Utilization and Quality</b> <ul style="list-style-type: none"> <li>• Cost effectiveness</li> <li>• Cost of care related to a regimen (resource utilization)</li> <li>• Patterns of Care</li> <li>• Practice population analysis</li> <li>• Quality of life measurement</li> <li>• Disease surveillance</li> <li>• Timeliness of care measurement</li> <li>• Financial analysis and reporting, including utilization</li> <li>• Outcomes analysis tools</li> <li>• Customizable reports</li> </ul>
4.9	1	<b>Communication:</b> <ul style="list-style-type: none"> <li>• Ability to send a report, referral, treatment summary to other providers electronically AND/OR printed copy to mail</li> <li>• Interoperable with lab, radiology, hospital information management system, other clinical system considered mission critical</li> <li>• Ability to machine read written reports (pathology)</li> </ul>
5.0		<b>Interoperability, Security and Data Standards:</b>
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.



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.		<b>Compliance Safeguards</b>
6.1	X	Privacy and Security safeguards in place
6.2	X	Disaster Recovery plan in place