October 6, 2009

CLINICAL ONCOLOGY REQUIREMENTS FOR THE EHR (CORE)

Clinical oncology involves many care processes, such as chemotherapy administration, that are not supported by the electronic health record (EHR) products currently on the market. The CORE project will provide a clear understanding of the EHR functions needed to support an oncologist in clinical practice, paving the way for development of oncology-specific products.

Clinical Oncology Requirements for the EHR (CORE)

A COLLABORATIVE PROJECT OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGYAND THE NATIONAL CANCER INSTITUTE

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INTRODUCTION

The **Clinical Oncology Requirements for the EHR (CORE)** project was undertaken by the American Society of Clinical Oncology (ASCO), the National Cancer Institute (NCI) Center for Biomedical Informatics and Information Technology, and the National Community Cancer Center Program (NCCCP) to specify the informatics needs of practicing oncologists.

Electronic health records (EHRs) promise to improve the safety, quality and efficiency of cancer care, leading to better outcomes for cancer patients and their care teams. Cancer is the second most common cause of death in the United States after heart disease. In 2005, there were about 560,000 cancer deaths in the U.S. Although mortality rates from cancer have declined slightly in recent years, the incidence of new cancers remains high. In 2008, experts estimate that there will be 1.4 million new cancer cases. Many Americans are affected by cancer. The lifetime risk of developing cancer is one in two for men. For women, the lifetime risk is one in three.[1] Cancer is also quite costly, with the National Institutes of Health estimating the overall costs of cancer in 2007 at $219.2 billion.[2]

If designed and implemented properly, EHRs can ensure that needed information is available at the time of care, facilitate coordination of care across the many providers involved in an individual's treatment, improve the safety and quality of care by expanding real-time access to clinical guidelines and other decision support tools, and enhance the efficiency of care by reducing the need for redundant tests. EHRs can also play an important role in advancing clinical research by enhancing physicians' ability to match patients to clinical trials and reducing the burden of participating in research activities.[3]

Clinical oncology involves many complex care processes unique in medicine, such as documenting the type and stage of cancer, providing oncology-specific flow-sheets, documenting chemotherapy treatment, creating multidisciplinary workflow documentation, integrating laboratory and imaging reporting, providing medication-related safety checks, and generating standardized treatment plans and summaries, and order sets, among others.[4] Existing EHR solutions vary in their functional capabilities and there is not a reference source that lists a detailed, consensus-driven set of core performance requirements for supporting oncology practice. Consequently, many oncologists are reluctant to commit to a system without the reassurance that a minimum standard has been met. Oncologists also face the financial and implementation challenges experienced by all physicians looking to adopt EHRs.[5]

The CORE Project brought together many practitioners and informaticists from ASCO, NCI and the NCCCP to detail the functional requirements, data element specifications, and interoperability requirements of an EHR that will support oncologists providing patient-centered care. They reflect the needs of a busy oncology practice in today's changing landscape, whether practices are academic or community-based.

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[1] American Cancer Society: Cancer Facts and Figures 2008. Available at: http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf.
[2] American Cancer Society: Cancer Facts and Figures 2008. http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf.
[3] Wallace PJ. Reshaping cancer learning through the use of health information technology. *Health Affairs*. 2007. Web Exclusive (January 26).
[4] R. Piana. Oncology electronic health records: More than just an e-secretary. *Oncology News International* 2008; 17(10) (October 1).
[5] Catherine M. DesRoches et al. Electronic health records in ambulatory care — a national survey of physicians. *NEJM* 2008; 359(1):50-60.

Project participants took patient-centered care as their starting point, emphasizing the need to better inform patients and coordinate care across providers to ensure continuity of care. The requirements document also lays out specific functions needed to support the advancement of medical science and increased efficiency of care. The functional requirements support safe, high-quality, patient-centered care by outlining how EHRs can support:

- A treatment plan to be shared with patients and other care providers;
- A treatment summary to be shared with patients and their care teams;
- The use of calendars that patients and their care teams can use to organize the care process;
- Safe chemotherapy administration; and
- Use of decision support tools, such as ASCO and National Comprehensive Cancer Network (NCCN) guidelines.

The document also outlines how EHRs can advance medical science by supporting physician participation in clinical research and decreasing the burden of such participation by, for example, linking to clinical trials and basic science research tools. Creating an electronic common Case Report Form to provide information on trial participants is the subject of a separate and ongoing ASCO/NCI collaborative project. By identifying structured data definitions, the requirements also lay the groundwork for population-level analysis and comparative effectiveness research. Finally, the requirements support greater efficiency and safety of care by supporting standardized workflows, documenting adherence to quality measures, and outlining tools for practice management and analysis.

POLICY CONTEXT

The CORE Project comes at an opportune time for the oncology field. In the American Recovery and Reinvestment Act of 2009, the federal government provided incentives for adoption of EHRs in both the Medicare and Medicaid programs. To receive the greatest benefit from those incentive programs, physicians and hospitals must begin using EHRs in 2011 and 2012. The federal government will establish eligibility criteria for these incentive programs based not just on the adoption of EHRs, but also on their "meaningful use" to improve care.

The CORE Project facilitates timely adoption of oncology-specific EHRs by outlining the functional requirements, data elements, and interoperability specifications of most benefit to the oncology field. In addition, the project outlines the ways in which oncologists expect to use EHRs, and may, therefore, provide valuable insights for regulators on what constitutes "meaningful use" of an oncology-specific EHR.

To further facilitate adoption of EHRs, ASCO with the support of NCI and the American Cancer Society (ACS) successfully petitioned the Certification Commission for Health Information Technology (CCHIT) to put certification of oncology-specific EHRs on its roadmap for 2011. The certification process can build on the specifications outlined in the CORE Project and provide an objective analysis of whether specific EHR products meet them. The oncology-specific certification would likely be in addition to the basic, "meaningful use" certification currently being contemplated as a requirement for receiving federal EHR incentive payments.

BACKGROUND

The CORE Project brings together the clinical expertise of practicing oncologists and the technical expertise of informaticists. It builds on past efforts of ASCO and NCI. On the clinical side, the project has its beginnings in the ASCO EHR Roundtable that took place in January 2007. The Roundtable was charged with developing recommendations to enable effective exchange of health information between patients with cancer and their caregivers. More than 40 thought leaders from all corners of the cancer community were involved, including government, academic centers, community-based oncology practices, commercial payers, oncology software vendors, and patient advocacy organizations.

At the Roundtable, participants identified the functional elements needed to capture chemotherapy administration in an EHR and facilitate information sharing about cancer care. The participants generated specific functional criteria and characterized them as either critical or desirable. The results of the Roundtable and the detailed listing of functional elements are documented in a report entitled "Ensuring Continuity of Care for Patients with Cancer through Electronic Health Records: Recommendations from ASCO's 2007 EHR Roundtable."[6] The project also builds on research on the role of EHRs in supporting safe chemotherapy practice, improving practice workflow, and enhancing clinical research.[7, 8, 9, 10] ASCO has also engaged EHR vendors in a series of symposia and vendor laboratories that facilitate the comparative evaluation by oncologists and their staff of vendor products.[11]

On the technical side, since 2004, NCI has developed standards-based infrastructure and tools to support the exchange of data from cancer research as part of the Cancer Biomedical Informatics Grid.® The caBIG® is an open-source, open-access information network enabling cancer researchers to share tools, data, applications, and technologies according to agreed-upon standards and identified needs. Many of the standardization efforts developed for the caBIG®, including vocabularies, data elements, and data models have been incorporated into and extended through the CORE Project.

STRUCTURE AND PROCESS

ASCO and NCI began their collaboration on the oncology-specific EHR early in 2008, and made a commitment to pursue the CORE Project in December 2008.

The project has three goals, undertaken by three workgroups:

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[6] Ensuring continuity of care through electronic health records. *J Oncol Pract* 2007; 3(3):137-142.
[7] LN Shulman et al. Principles of safe practice using an oncology EHR system for chemotherapy ordering, preparation, and administration, Part 1 of 2. *J Oncol Pract* 2008; 4(4):203-206.
[8] LN Shulman et al. Principles of safe practice using an oncology EHR system for chemotherapy ordering, preparation, and administration, Part 2 of 2. *J Oncol Pract* 2008; 4(5):254-257.
[9] J Goldwein. Using an electronic health record for research. *J Oncol Pract* 2007; 3(5):278-279.
[10] Wallace PJ. Reshaping cancer learning through the use of health information technology. *Health Affairs* 2007. Web Exclusive (January 26).
[11] Specifically, ASCO has invited vendors to participate in the 2007 EHR Roundtable; challenged vendors to develop products that can generate a treatment plan and summary; conducted both an annual EHR Vendor Laboratory and an EHR Symposium since 2007; and developed an EHR Vendor Directory that provides basic information on 20 vendors that offer oncology-related solutions.

- Describe the functions oncologists want an EHR to perform (Functional Requirements Workgroup);
- Provide the structured data elements to be used in oncology EHRs (Data Elements Workgroup); and
- Provide a common set of interoperability standards that will allow oncology-specific data to be shared from one EHR to another (Interoperability Workgroup).

To achieve those objectives, about three dozen ASCO volunteers, NCI staff, and participants from the NCCCP have engaged in regular meetings over the course of six months. During that time, hundreds of hours of volunteer effort have been dedicated to producing the requirements documents.

The CORE Project also solicited feedback from the oncology community, vendors, and other interested parties to get reactions from multiple perspectives. The functional requirements were posted on a public website and comments were solicited from both the oncology and vendor communities. Requirements were posted at: https://wiki.nci.nih.gov/display/CTMS/Clinical+Oncology+Requirements+for+the+EHR+Community+Review. The vendor community received a preview of the requirements in September 2009. A full set of technical specifications were released at the ASCO EHR Symposium in October 2009.

FUNCTIONAL REQUIREMENTS

The Functional Requirements Workgroup considered the information collection, decision support, and reporting needs of the oncologist providing patient-focused care in a clinical setting. Using an iterative, consensus-based process, the group outlined the key types of data and functions oncologists need to support four categories of functionality:

- Generate and transmit a cancer treatment plan;
- Generate and transmit a cancer treatment summary;
- Support oncology-specific documentation; and
- Support oncology-specific EHR functionality.

The high-level requirements document is attached as Appendix 2. Some examples of the data and functionality outlined in each category follow.

Cancer Treatment Plan. The plan for a course of treatment includes demographic and diagnostic information, such as diagnosis, tumor staging, pathology findings, and co-morbid conditions. In addition, the plan outlines the information needed to describe both prior treatment and the current treatment plan, such as surgeries, procedures, chemotherapy regimens, and potential toxicities. To enhance participation in clinical trials, the functional requirements also include a field for a clinical trial protocol number, where relevant, and a link to the pertinent clinical trial protocol document.

Cancer Treatment Summary. The summary of course of treatment includes much of the information from the treatment plan, but also includes information on any chemotherapy and biotherapy delivered, major toxicities experienced, and palliative care or hospice plans. A section on follow-up care provides information on who will provide the care, as well as needed tasks and expected timelines for monitoring the patient for disease recurrence and long term adverse effects from treatment that includes a calendar function.

Oncology-Specific Documentation. The section on oncology-specific documentation details the type of flow sheets that are needed by oncologists and information that will support them. It also notes that individual practice sites will likely want to configure the flow sheets to support their practice management needs, in addition to configurations by cancer type. Oncology-specific medical record fields include, for example, tumor staging, radiation reports, and chemotherapy records. The requirements document also lists more general elements of the medical record important to oncologists, such as pain assessment, pathology reports, patient consent forms, and end-of-life documents.

The Workgroup identified numerous types of decision-support tools specific to oncology, including, for example, access to guidelines developed by ASCO and NCCN, cancer staging guidelines, and pain management tools. In addition to incorporating guidelines from outside organizations, the Workgroup noted the importance of having software that incorporates institution-specific guidelines and workflows.

To support participation in clinical trials, the Workgroup also identified the need to include in the EHR tools for assessing individual patients' eligibility for specific clinical trials, as well as access to clinical trial summaries that can be shared with the patient.

To encourage patient participation in decision-making, the Workgroup identified the need to include in the EHR a checklist of patient education materials and needed consultations, as well as access to national and locally developed patient education resources.

Oncology-Specific Functionality. Consistent with the Workgroup's focus on safe, patient-centered care, the functional requirements include detailed analysis of functions to support chemotherapy and drug management. The chemotherapy ordering system, for example, should facilitate electronic orders, interface with the pharmacy system, and allow nursing and pharmacy staff to electronically perform the safety check of verifying orders after they have been approved by a physician or nurse practitioner, but before the chemotherapy administration begins.

An oncology-specific EHR would also support the ordering of chemotherapy and other drugs by, among other things, including standardized order sets and assisting in dose calculations, including calculations based on height, weight, and lab results. The requirements document includes a strong list of features needed to support safe chemotherapy and management of supportive medications, such as anti-emetics. Safety measures should include, for example, steps such as tracking lifetime cumulative doses of chemotherapy drugs and providing alerts on allergies and possible drug-drug interactions.

To support coordination of care, the Workgroup identified a number of scheduling functions important to practicing oncologists, such as the ability to schedule physician visits, education/training sessions, lab and radiology tests, infusions, and injections. To support patients, EHRs should have the capacity to print calendars and generate reminders. As appropriate, this information can be included in a patient portal.

The Workgroup also noted functions that support other elements of oncology practice, including:

- Inventory control and billing functions;
- Specific tools to support clinical trials and research;
- End-of-life care management tools;

- Integration of bar-coding or RFID technology to support patient identification and matching to prescribed medications and lab/pathology samples;
- Generation of quality metrics and other population-based reports;
- Capacity to generate and communicate to others treatment plans, summaries, and other reports; and
- Capacity to provide a patient portal with personal health record (PHR) capability.

CLINICAL DATA ELEMENTS

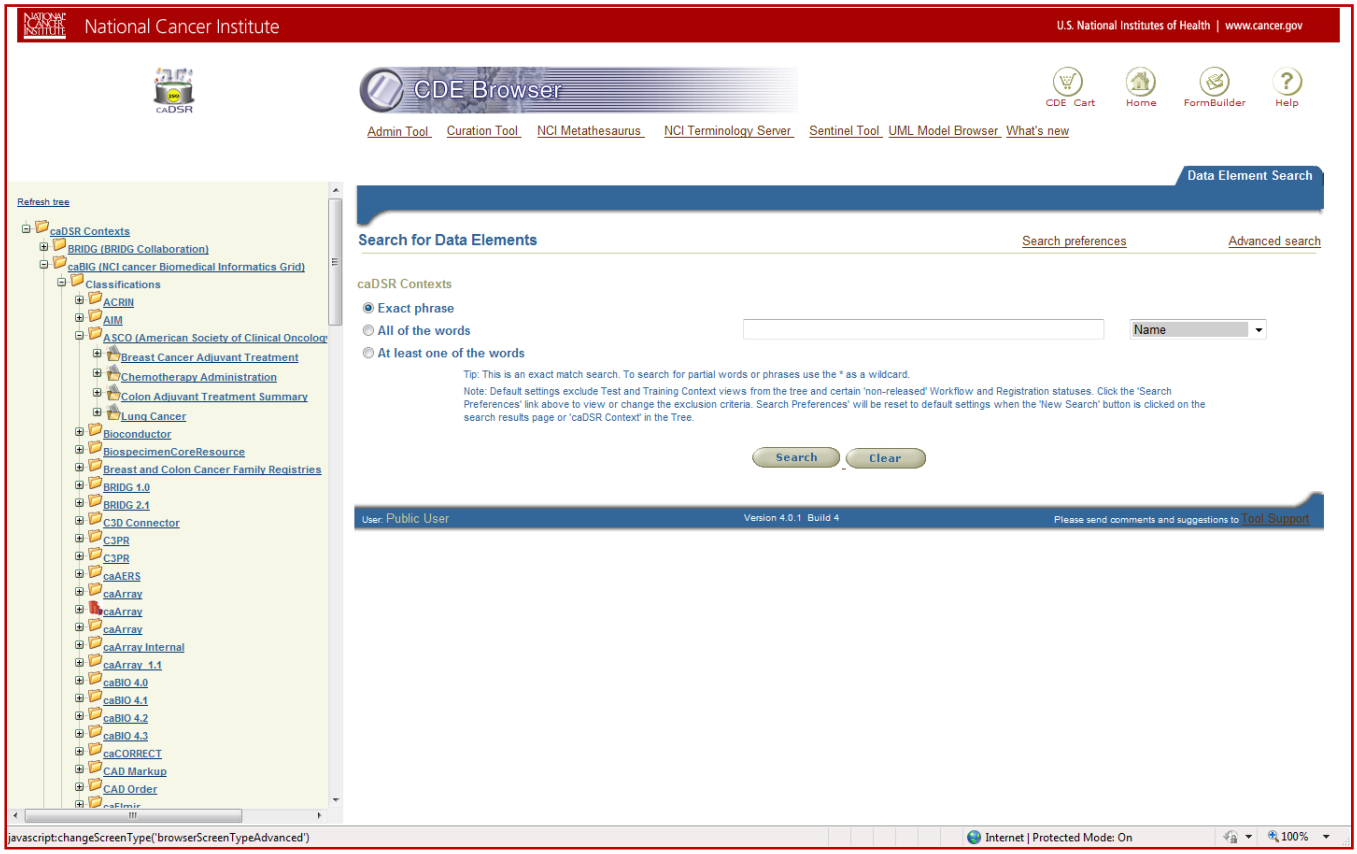
For health information to flow among providers and patients, it must be presented in a form that allows for common identification of data elements and their meaning. The development of structured data elements with specific definitions built from clinically relevant terminology facilitates information sharing while minimizing the chances of misinterpretation or ambiguity. It also facilitates analysis of data to support clinical operations, improve quality, and enhance research.

Given the volume of information contained in a medical record, creating common definitions can be a significant undertaking. The NCI has taken on this challenge by establishing the Cancer Data Standards Repository (caDSR), an on-line metadata registry that was developed to share and standardize the set of variables used in cancer clinical trials. Data elements are generated and registered in the caDSR to meet trial needs and become part of caDSR's rich set of variables and forms, many of which are useful in multiple clinical areas, not just cancer care. Numerous bioinformatics projects, such as the development of a common set of Case Report Forms to collect clinical trial information, also reuse and extend the content of the caDSR.[12]

The Clinical Data Elements Workgroup based its work on information needed to generate treatment plans and summaries for three common types of cancer: breast, colon, and lung. In addition, the group looked at data elements required to document chemotherapy administration. The treatment summary and plan provides information on the type, site, and stage of cancer; surgeries and other procedures performed; chemotherapy and other drugs administered; and potential side effects and adverse reactions. The plans and summaries also include contact information for the patient and his or her support contacts as well as the names and contact information for the treatment team (see Appendix 3 for the breast cancer treatment plan and summary).

After identifying needed information, the Workgroup first focused on the reuse of data elements already in the caDSR. This principle of "reuse first" was practiced before the creation of any new elements. In total, nearly 200 data elements were defined to support the treatment summaries and chemotherapy documentation. Of those, nearly 70 percent re-used existing data elements and standards. As might be expected, the four clinical scenarios had many data elements in common. The caDSR is available at https://cdebrowser.nci.nih.gov/CDEBrowser/.

[12] For more information on the caDSR, see http://ncicb.nci.nih.gov/infrastructure/cacore_overview/cadsr.



INTEROPERABILITY

The Interoperability Workgroup discussed multiple approaches to specifying requirements for an oncology-specific EHR so that it can share computable information with other information systems. Achieving interoperability will require consideration of specifications unique to oncology within the context of the work being done in the larger informatics community to share clinical and research data. Additionally, interoperability requirements for an oncology EHR will need to conform to forthcoming federal regulations on health information technology standards, building on recommendations from the newly formed Health Information Technology Standards Committee.

To further this work, NCI and ASCO plan to submit an HL7 Oncology EHR functional profile to the HL7 standards development organization for ratification, as an extension of the HL7 Electronic Health Record System Functional Model. NCI and ASCO will submit the project documentation to HL7 to establish a formal project within the HL7 EHR working group following the ASCO EHR Symposium in October 2009.

In a separate, short-term initiative, the NCI plans to build a set of specifications on a prior model of the static semantics of clinical care within the ambulatory oncology setting — the Biomedical Research Integrated Domain Group (BRIDG) model. BRIDG is a collaborative initiative between the NCI, the Clinical Data Interchange Standards Consortium, the Regulated Clinical Research Information Management Technical

Committee of Health Level 7 (HL7), and the Food and Drug Administration to develop a model of the shared understanding of the semantics of clinical research. Note, however, that NCI will use BRIDG merely as a starting information model to define the static semantics of oncology EHRs — the fact that clinical research and clinical care share some common semantics will allow NCI to reuse them, as opposed to starting with a blank sheet of paper.

FUTURE DIRECTIONS

Next steps will include constructing reference implementation models that help to:

- Assess functionalities that may have been missed and need to be captured for more complete support of the oncology clinical care enterprise;
- Determine the extent to which currently available products as presently designed and configured can support these oncology functionalities;
- Perform a gap analysis between the functionalities achievable with currently rendered vendor EHR products and those oncology functionalities which will require development of new software design (in some case, novel use of existing software design may allow earlier introduction of needed functionality);
- Identify which functionalities may be better achieved through use of alternative applications and databases outside of the EHR itself, rather than redirecting EHR development (alternative applications could be made available through interfaces to the EHR or through datamart/cloud computing architectures).

To achieve these objectives, the NCI plans to take the requirements developed through the CORE Project and build an open source reference implementation of the specification, caEHR, in 2010. This oncology extension for the EHR can be incorporated by vendors and other developer groups to create compliant oncology EHR solutions.

The caEHR effort will build on the specifications developed as part of the CORE Project. The interoperability specifications continue to be refined under caEHR. The latest draft is available at: https://wiki.nci.nih.gov/display/EAWiki/Line+of+Business+-+caEHR.

In parallel to this effort, reference implementation models that build upon existing commercial products will need to be constructed and studied. The diverse nature of the data that support cancer care and research often means that it resides in multiple databases and not exclusively in an EHR. Complex health care systems engaged in research and clinical care have already invested heavily in HIT resources, usually in an uncoordinated fashion. As a result, much of the clinically useful data now exists in separate databases that are not interoperable. A pragmatic approach dictates the study of robust health care delivery systems that have already implemented sophisticated health information technology solutions to evaluate how cloud architecture can link information residing in separate data bases for the support of the oncology enterprise.

Next steps will also include refining the data models that support interoperability, including:

- Developing an oncology EHR functional profile through HL7 that aligns with the interoperability specifications derived from federal standards harmonization activities;
- Defining the content and functions required by personal health record systems (PHRS), as well as how oncology specific EHRS would interact with a PHRS;
- Incorporating standards for representation of patient symptoms, which are currently in development,[13] with the explicit goal of enabling oncology patients to self-record pain, nausea, vomiting, depression, anxiety and related targets for palliative care; and
- Identifying and defining, through collaboration with other partners in the cancer care community, those data elements from an EHR which are required for reporting to cancer registries, needed by clinical decision support, or are of use in quality of care measures.

We also anticipate a more rigorous evaluation of how the oncology EHR can support the conduct of clinical trials. Areas of interest include tracking of investigational drug procurement, storage and administration; decision support for protocol-mandated dose modifications; more complete capture of protocol-specified data elements; compliance with regulatory documentation; and streamlining the audit process.

CONCLUSION

It is time to realize the promise of EHRs to improve health care for cancer patients and their care providers. By pursuing a collaborative process that brings together clinical, technical, and research knowledge, the CORE Project lays solid groundwork for development of oncology-specific EHRs and alternative technologies to support clinical oncology by multiple vendors. The requirements outlined here will also guide development of certification criteria so that practicing oncologists can be assured their EHR and other technology investments will be useful. The oncology field continues to pursue both scientific and practice-based knowledge to improve cancer care. Widespread availability of interoperable EHRs and other oncology-specific solutions that support patient-centered care, care improvement, and participation in research will accelerate our progress.

[13] For example, by the HL7 Patient Care workgroup.

APPENDICES

1. List of Workgroup Volunteers
2. CORE Functional Requirements Document
3. ASCO Breast Cancer Adjuvant Treatment Plan and Summary

APPENDIX 1: WORKGROUP VOLUNTEERS

Data Elements Workgroup:

Edward P. Ambinder, MD – ASCO EHR Workgroup member; Clinical Professor of Medicine, Mount Sinai School of Medicine; practicing oncologist.
Dianne Reeves, RN, BSN – Associate Director for Biomedical Data Standards, NCI Center for Biomedical Informatics and Information Technology
Amar Das, MD – Physician and Associate Professor of Bioinformatics, Stanford University
Wei-Nchih Lee, MD – Internist; Stanford PhD student in biomedical informatics

Functional Requirements Workgroup:

Peter Yu, MD – ASCO EHR Workgroup Chair; ASCO Board of Directors member; Director of Oncology Research and practicing oncologist at the Palo Alto Medical Foundation
Brenda Duggan, RN, BSN – National Community Cancer Center Program Information Technology Program Manager, NCI Center for Biomedical Informatics and Information Technology
Amar Das, MD, PhD – Physician; Assistant Professor of Medicine (Medical Informatics), Stanford University
Herb Kaizer, MD – Oncologist; collaborating domain expert
Mia Levy, MD – Assistant Professor, Biomedical Informatics and Medicine, Cancer Clinical Informatics Officer, Vanderbilt University
Nancy Sklarin, MD – Oncologist and Director of Chemotherapy Practice, Memorial Sloan-Kettering Cancer Center
Mary Parker – NCCCP Lead/ Coordinator, Ascension Health - National
Saundra Sheets – NCCCP IT Contact, Ascension Health - St. Vincent's
Andrea Gaudiosa – Director, IT Operations, Columbia St. Mary's
Valerie Griffin – ASIS Architect, Seton
Sarah Osen – NCCCP Coordinator, Billings Clinic Cancer Center
Deb Hood – NCCCP Project Director, Catholic Health Initiatives (CHI)
Debbi Honey – VP Clinical Operations, CHI National
Lance Groves – Data Manager, CHI - St Joseph/Towson Hospital
Jeanne Barnes – Director, Information Technology, CHI - Good Samaritan Hospital
Mary Kielma – Director, Pathology Laboratory, CHI-Penrose Hospital
Rajiv Haravu – NCCCP IT Coordinator, Helen F. Graham Cancer Center at Christiana Care
Pat Montanaro – Director, EHR Information Services, Helen and Harry Gray Cancer Center
Maegan Dunn – NCCCP IT Coordinator, Our Lady of the Lake Cancer Center
Erdal Sipahi – Director, Mission Information Technology, Mary Bird Perkins Cancer Center
Holly Johnson, PMP – NCCCP IT Coordinator; Sanford Research IT Project Manager, Sanford USD Medical Center
Lucy Gansaur – NCCCP Services Director, Gibbs Cancer Center
Beverly Albury – Manager, Information Technology, Lewis Cancer & Research Pavilion at St. Joseph's-Candler
Nancy Johnson – Executive Director, Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's-Candler
Nancy Harris – Administrator Cancer Services, St. Joseph Hospital of Orange
Joshua Mann – NCCCP IT Specialist, The Center for Cancer Prevention and Treatment

Interoperability Specifications Workgroup:

Kevin Coonan, MD – Clinical Research Informatics and Knowledge Management, Dana-Farber Cancer Center
George Komatsoulis, PhD – Director, Quality Assurance and Compliance at the National Cancer Institute Center for Biomedical Informatics and Information Technology
Mia Levy, MD, PhD – Assistant Professor, Oncology Vanderbilt University
Philip Strong, MD – Palo Alto Medical Foundation

APPENDIX 2: CORE FUNCTIONAL REQUIREMENTS DOCUMENT

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
1		*Plan for Course of Treatment* *drop down menu to select, neoadjuvant, adjuvant, curative, advanced* *drop down menu to select, treatment 1, treatment 2, treatment 3, treatment 4, etc…* **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*
1.1		DEMOGRAPHICS
1.1.1	1	Patient Demographics Name, DOB, MRN Contact information, NOK, Emergency contact Race and ethnicity Language preference (optional field)
1.1.2	1	Treating physicians and their sub specialty area/Primary physicians Name, Sub-specialty, Address, Phone, Fax, Mobile, E-mail
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) Site Histology/pathology Biomarkers (ER, HER2, c-Kit etc) Molecular markers (bcr+ etc) Chromosomal markers
1.2.3	1	Primary Staging 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. grade, 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, site)
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, field, dose, adverse effects)
1.4		CURRENT PLAN
1.4.1	1	Intent/goals of therapy (neo-adjuvant, adjuvant, curative, advanced /palliative)
1.4.2	1	Performance status (including Karnofsky, etc…), specify type

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
1.4.3	1	Sites of disease being monitored 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 (site, field, dose)
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.		*Summary of Course of Treatment* *(longitudinal treatment/disease tracking tool w/each course of therapy, broken out: Neoadjuvant, Adjuvant; etc… that builds through time; accumulative)* **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*
2.1		DEMOGRAPHICS
2.1.1	1	Patient demographics Name, DOB, MRN Contact information, NOK, Emergency contact Race and ethnicity Language preference (optional)
2.1.2	1	Referring/Primary physicians Name, Sub-specialty, Address, Phone, Fax, Mobile, E-mail
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) Site Histology/pathology Pathologic features of primary site (e.g. grade, transformed lymphoma) Biomarkers (ER, HER2, c-Kit etc) Molecular markers (bcr+ etc) Chromosomal markers

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
2.2.3	1	Primary Staging 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, site)
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, field, dose, adverse effects)
2.4.4		CURRENT TREATMENT
2.4.5	1	Intent/goals of therapy – (neo-adjuvant, adjuvant, curative, advanced /palliative)
2.4.6	1	Chemotherapy/biotherapy delivered – intravenous and oral Protocol # (if applicable) Height, weight, BSA Dose/m2(kg), treatment dose Number of cycles planned and administered 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, patient refusal)
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), Dose, Field, Response, Adverse Effects)
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…); specify type
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, mobile, e-mail

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
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 Further therapy needed Followup frequency Testing & time frame
2.5.4	1	Signature line with treating physician's contact information
3.		*Oncology-Specific Documentation*
3.1	1	Flow Sheets: preferably configurable by site to include the following sections Treatment regimen summary table regimen start and stop date response Ongoing treatment (configurable for disease specificity) Chemotherapy treatment (intravenous and oral) Other medications Transfusions Radiation Vital signs 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: 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 Laboratory reports Imaging reports Consents End of life documentation – scanned documents to include: DNR, etc…

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
3.3	1	Cause of Death/Date of Death 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	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 teaching pamphlets/handouts, as well as internally authored pamphlets/handouts and templates
4.		*Oncology Specific EHR Functionality*
4.1.		Chemotherapy/Drug Management –
4.1.1.		Chemotherapy ordering system
4.1. 1.2	1	ability to order electronically
4.1. 1.3	1	to interface with pharmacy system
4.1. 1.4	1	to interface with electronic medication administration record
4.1. 1.5	1	ability to choose from predetermined regimen order sets of standard regimens or study protocols (configurable per institution)
4.1. 1.6	2	electronic link to protocol from the order
4.1.	1	ability to have dates fill in automatically for multiday/week therapy

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
1.7		
4.1.1.8	1	ability to reorder from prior cycle
4.1.1.9	1	ability to modify orders/doses
4.1.1.10	1	document treatment parameters on order
4.1.1.11	1	signing off electronically on each cycle
4.1.1.12	1	verify orders electronically by nursing and pharmacy after MD/NP signs
4.1.1.13	1	Ability to use the previous height/weight or apply the new height/weight
4.1.1.14	1	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	Chemotherapy dosing functions 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

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
4.1.3	1	Safety guardrails within electronic ordering 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	Supportive medication management/order sets 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	must be able to interface with an existing billing management system and a drug inventory control system:
4.2.2	1	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) *Note*, these pharmacy functionalities could be handled outside of the EHR by the pharmacy management system.
4.2.3	1	Ability to track the source of the drug – pharma, clinical trial, vendor (customizable) oncology specific but should be part of the pharmacy system *Note,* these pharmacy

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
		functionalities could be handled outside of the EHR by the pharmacy management system.
4.2.4	1	Chemotherapy coding (J-codes) and reimbursement management should be part of a pharmacy system
4.2.5	1	Oncology specific procedure codes and drug administration billing codes (time dependent) for total record of charges
4.2.6	1	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	Billing office alert for all drugs/treatments to approve/authorize.
4.2.8	1	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	Ability to schedule regimens/full course of care, to include: Physician visits Education/training Lab/radiology Infusion Injections
4.3.2	1	Ability to update the calendar easily and push dates accordingly
4.3.3	1	Chemo chair scheduling
4.3.4	1	Ability to print off calendar of treatments, lab and radiology appointments, physician appointments to give to patient
4.3.5	1	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	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: 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	Clinical trials and research tools (caBIG)
4.4.2	1	Investigational drug documentation with the ability to customize to meet the needs of each sponsors requirements – links to protocol
4.4.3	1	Clinical trial accrual monitoring and screening logic (NCCCP CT Screening and Accrual log captures all of this information…see attached) If patient accrued to a trial, which trial did they accrue to

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
		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	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	End of Life Tools: ability to print templates for patient and ability to scan and save signed copies. Health care proxies Living wills Power of attorney Do Not Resuscitate (DNR)
4.6	X	Patient Portal: Ability for patient to provide information to the provider electronically, such as: Performance status Pain control Quality of life Medication record Holistic/alternative therapies Access to the patient's medical record Access to lab/radiology results Personal health record Provide education pamphlets (links to ASCO, NCI, and ability to import organizations own teaching materials), template medication records, etc… Medical device monitoring management
4.7	3	Bar-Coding/Labeling: 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 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

ID	Priority 1 = essential 2 = desired 3=eventually X=needs prioritization	Element/Functionality
		Outcomes analysis tools Customizable reports
4.9	1	Communication: 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.
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 XXXXXXXXXXXXXXXXXXX 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

APPENDIX 3: ASCO BREAST CANCER ADJUVANT TREATMENT PLAN AND SUMMARY (VERSION 2.0, 01/08)

The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.

Medical oncology provider name:

Patient name:		**Patient ID**:
Patient DOB: (___/___/___)	**Age at diagnosis**:	**Patient phone**:
Support contact name:		
Support contact relationship:	**Support contact phone**:	

BACKGROUND INFORMATION

Breast cancer site: ? Left breast ? Right breast ? Bilateral

Family history: ? None ? 2nd degree relative ? 1st degree relative ? Multiple relatives

Definitive breast surgery: **Date**:(___/___/___) **Type**: ? Lumpectomy ? Mastectomy ? Mastectomy/immediate recon

# lymph nodes removed:	**# lymph notes positive**:
Axillary dissection: ? Yes (___/___/___) ? No	**Sentinel node biopsy**: ? Yes (___/___/___) ? No

Notable surgical findings/comments:

Tumor type: ? Infiltrating ductal ? Infiltrating lobular ? Other: _____

T stage: ?T1 ?T2 ?T3 ?T4a ?T4b ?T4c ?T4d	**N stage**: ? N0 ? N1 ? N2 ? N3
Pathologic stage: ? 0 ? I ? II ? III	**Oncotype DX recurrence score (if applicable):**

ER status: ? Positive ? Negative	**PR status**: ? Positive ? Negative	**HER2 status**: ? Positive ? Negative

Major comorbid conditions:

Echocardiogram or MUGA result prior to chemotherapy (if obtained): EF= %

ADJUVANT TREATMENT PLAN | **ADJUVANT TREATMENT SUMMARY**

White sections to be completed prior to chemotherapy administration, shaded sections following chemotherapy

Height: in/cm	**Pre-treatment weight:** lb/kg	**Post-treatment weight:** lb/kg
Pre-Treatment BSA:	**Date last menstrual period**:(___/___/___)	**Date last menstrual period**: (___/___/___)

Name of regimen:

Start Date: (___/___/___)	**End Date:** (___/___/___)

Treatment on clinical trial: ? Yes ? No

Chemotherapy Drug Name	Route	Dose	Schedule	Dose reduction needed	Number of cycles administered
				? Yes _____% ? No	
				? Yes _____% ? No	
				? Yes _____% ? No	
				? Yes _____% ? No	

Possible side effects of this regimen:
? Hair loss ? Nausea/Vomiting ? Neuropathy
? Low blood count ? Fatigue
? Menopause symptoms ? Cardiac symptoms
? Other:

Anthracycline administered: ? **Doxorubicin** _____ mg/m^2
? **Epirubicin** _____mg/m^2

Serious toxicities during treatment (list all):

Radiation therapy planned: ? Yes ? No
Date completed: (___/___/___)

Hospitalization for toxicity during treatment: ? Yes ? No

Neurotoxicity that impairs activities of daily living: ? Yes ? No

Reconstruction planned: ? Yes ? No
Date completed:(___/___/___)

Reason for stopping adjuvant treatment:

Important caution: this is a summary document whose purpose is to review the highlights of the breast cancer chemotherapy treatment plan for this patient. This does not replace information available in the medical record, a complete medical history provided by the patient, examination and diagnostic information, or educational materials that describe strategies for coping with breast cancer and adjuvant chemotherapy in detail. Both medical science and an individual's health care needs change, and therefore this document is current only as of the date of preparation. This summary document does not prescribe or recommend any particular medical treatment or care for breast cancer or any other disease and does not substitute for the independent medical judgment of the treating professional.

The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.

ADJUVANT TREATMENT PLAN	ADJUVANT TREATMENT SUMMARY
ENDOCRINE THERAPY	
?**None** ?**Tamoxifen** ?**Aromatase Inhibitor** ?**Other**	**Date endocrine therapy started (or to start)** (___/___/___)
Medication:	
Duration:	
TRASTUZUMAB (HERCEPTIN) THERAPY	
Trastuzumab (Herceptin) planned: ?Yes ? No	**Trastuzumab (Herceptin) prescribed**: ?Yes ? No
	Pre-trastuzumab ejection fraction: %(___/___/___)
	Most recent ejection fraction: %(___/___/___)
	Planned or completed dates of trastuzumab therapy: Start date (___/___/___) End date (___/___/___)
ONCOLOGY TEAM MEMBER CONTACTS	**SURVIVORSHIP CARE PROVIDER CONTACTS**
Provider:	**Provider:**
Name:	Name:
Contact Info:	Contact Info:
Provider:	**Provider:**
Name:	Name:
Contact Info:	Contact Info:
Provider:	**Provider:**
Name:	Name:
Contact Info:	Contact Info:
Provider:	**Provider:**
Name:	Name:
Contact Info:	Contact Info:
Provider:	**Provider:**
Name:	Name:
Contact Info:	Contact Info:
Pre-treatment comments	**Post-treatment comments**

Important caution: this is a summary document whose purpose is to review the highlights of the breast cancer chemotherapy treatment plan for this patient. This does not replace information available in the medical record, a complete medical history provided by the patient, examination and diagnostic information, or educational materials that describe strategies for coping with breast cancer and adjuvant chemotherapy in detail. Both medical science and an individual's health care needs change, and therefore this document is current only as of the date of preparation. This summary document does not prescribe or recommend any particular medical treatment or care for breast cancer or any other disease and does not substitute for the independent medical judgment of the treating professional.