ASCO’s Oncology Rapid Learning System (RLS): What’s in it for Researchers?

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Agenda

• What is a RLS
• The Need for a RLS
• What can Researchers get from a RLS
• How is ASCO proceeding
What is a Rapid Learning System?

A simple description…

• A system in which real-time clinical data is captured, analyzed, and used to enhance patient care and drive scientific discovery
ASCO’s Oncology RLS

The Need

“Quality is Job One”
The Need

Pinto's little options.

Accent Group (illustrated at right). It's that little something extra that can make all the difference. With this group you get the following: bright window trim, rear door and one molding, wheel covers and wheel lip moldings. And inside, a carpet that's color-coordinated.

Protection Group (also shown at right). A smart buy if you do a lot of parking in shopping centers and city streets. Side moldings with vinyl inserts are a barrier when the parking next to you opens his door against yours. Bumper guards and bumpers have rubber inserts...for people who have a little trouble in tight spots.

Luggage Rack. This sculptured piece of chrome lets you carry all sorts of extras and makes going on vacation a Money event.

Rallye Appearance Group. For people who like the look of moving out...even when standing still. In this package you get a black grille with a Rallye Badge, black side lamp bezels, black or gold hood paint treatment and a black painted rear deck panel...with ASCO®...
The Need

- Health Care Practitioners:
  - Real time information to stay current with evolving research, evidence, and guidelines
  - Real time decision support tools to make treatment decisions in an increasingly difficult environment
  - Real time Quality measures and benchmarking to drive higher quality, lower cost care with better outcomes
The Need

• Patients:
  – to become more informed decision makers and contributors to their own care
  – to have the ability to manage adverse events with evidence based options
  – To communicate in real time with caregivers and healthcare providers

• Payers:
  – A way to demonstrate quality and cost-effective care

• Researchers:
  – to streamline and speed up scientific discovery
  – to reduce time to identify key events and make changes
The Vision: IOM ‘Rapid Learning System for Cancer Care’

- “In this framework, routinely collected real-time clinical data drive the process of scientific discovery, which becomes a natural outgrowth of patient care”
  - Abernethy et al, Rapid-Learning System for Cancer Care, JCO 2010

Why ASCO?

- ASCO has been in the “quality” business for at least fifteen years. One could argue that the very founding of the Society in 1964, intended to facilitate the exchange of clinical and scientific information, was designed to improve the quality of cancer care.
- Trusted & respected source for oncologists and oncology information
- QOPI®
Turning the Vision into Reality

The ASCO Board of Directors has adopted several guiding principles for RLS.

1. Rigorous – the hallmarks of RLS will be methodological rigor and comprehensiveness.

2. Patient focused – RLS will optimize reduced morbidity and mortality and incorporate the humane values of the profession.

3. Transparent – the methodology of RLS and the incentives of every collaborator and contributor will be visible.

4. Independent – the credibility of RLS depends on oncology peer decision-making and collaboration without compromise of principles. There will be a firewall between industry and guideline and standards development.

5. Inclusive – ASCO and CCF are open to collaborating with any organization, public or private, that accepts these Collaboration Principles. RLS will be accessible and usable from non-ASCO platforms.

6. Streamlined – RLS data collection will be efficient and not burdensome to providers.

7. Sustainable – ASCO has made a substantial investment in RLS and needs a sustainable economic model. Any commercialization of RLS will be support ASCO’s educational and quality endeavors.
Turning the Vision into Reality

• ASCO’s Real-Time Oncology Knowledge Network
  – harness cutting-edge HIT to connect cancer patients and their providers to a central knowledge base
  – synthesize information from millions of physician and patient experiences
  – Form a continuous cycle of learning
    • evidence → guidelines → aggregation/quality measurement → evidence
  – deliver up-to-the-minute, personalized information that allows every patient to receive the highest quality care

Utilizing a RLS for Research

• Quality and Guidelines
  – Ability to test and report on Quality measures and indicators
  – Ability to evaluate and inform formal guidelines
Utilizing a RLS for Research

• Health Outcomes Studies
  – Longitudinal data
  – Rich clinical data
  – Billing data/possible claims data
  – Outcomes could be captured or calculated
  – Ability to query patients through patient portal

• Population Health/Epidemiology Research
  – Large population to evaluate
  – Longitudinal data
  – Easy to match patients and identify control groups
  – “Real Time” allows for immediate identification of signal events
  – Ability to query patients through patient portal
Utilizing a RLS for Research

• Comparative Effectiveness Research
  – Will have diagnosis, stage, PS, etc.
  – Will have drug regimens and doses
  – Will have billing data
  – May have outcomes
  – Large population, longitudinal data

Utilizing a RLS for Research

• Clinical Trials
  – May be able to match patients to open clinical trials
  – May help identify regimens to be studied in other diseases
  – May speed up the process of drug development
Utilizing a RLS for Research

• Other Research
  – Behavioral Research (provider, patient, etc.)
  – Overall Quality Improvement
  – Caregiver research
  – Impact of technology on patient care
  – Preference studies
  – Etc.

Turning the Vision into Reality

• Work towards the goal:
  – New Hires & Advisory Group
  – PMO workgroups
  – Process Charts/Timelines
  – Technology Summit
Turning the Vision into Reality

• New Hires
  – Robert Hauser, PharmD, PhD
  – Kristen McNiff, MPH
  – Josh Mann

• Advisory Group
  – Dr. George Sledge & Dr. Cliff Hudis (co-chairs)
  – Dr. Amy Abernethy
  – Dr. Ethan Basch
  – Dr. Doug Blayney
  – Dr. Craig Earl
  – Dr. Mike Neuss
  – Dr. Larry Shulman
  – Dr. Peter Yu
  – Dr. Allen Lichter

Turning the Vision into Reality

• PMO workgroups
The TOGAF® Architecture Development Method

Where we are…

• **The Preliminary Phase** describes the preparation and initiation activities required to implement an architecture, including the definition of principles.

• **Phase A: Architecture Vision** describes the initial phase of an architecture development cycle (i.e. defining the scope, identifying the stakeholders, creating the Architecture Vision, and obtaining approvals).

• **Phase B: Business Architecture** describes the development of a Business Architecture to support the agreed Architecture Vision (i.e. Use cases, process diagrams, and class models).

The TOGAF® Architecture Development Method

What is coming…

• **Phase C: Information Systems Architectures** defines the applications and data considerations that support the Business Architecture; (i.e. defining views that relate to information, knowledge, application services, etc.)

• **Phase D: Technology Architecture.** This phase maps the application components defined in the Application Architecture phase into a set of technology components, which represent software and hardware components.

• **Phase E: Opportunities & Solutions** conducts initial implementation planning and the identification of delivery vehicles.

• **Phase F: Migration Planning** addresses the formulation of a set of detailed sequence of transition architectures with a supporting Implementation and Migration Plan.

• **Phase G: Implementation Governance** defines architectural oversight for the implementation.

• **Phase H: Architecture Change Management** establishes procedures for managing change to the architecture.

• **Requirements Management** examines the process of managing architecture requirements throughout the ADM.
ADM/IT Planning

• Detailed ADM/IT project plan for the RLS Pilot
• Pilot to begin soon

The RLS Infrastructure Architecture Principles

• Principle 1: Common Vocabulary and Data Definitions
• Principle 2: Data is an Asset
• Principle 3: Data Stewardship and Harmonization
• Principle 4: Data Integrity
• Principle 5: Data Security and Access
• Principle 6: Openness means interoperability
• Principle 7: Technology will be scalable and flexible
• Principle 8: Systems should be autonomous
• Principle 9: Buy before build
• Principle 10: Requirements-Based Change
• Principle 11: Responsive Change Management
The RLS Architecture Principles

Principle 1: Common Vocabulary and Data Definitions

Statement:
Data is defined consistently throughout the RLS and connecting systems. In addition, the definitions must be clear, concise, and available to users, participants and the public.

Rationale:
The data that will be used in the RLS must have common vocabularies and definitions, based on existing standards whenever possible. This is required to successfully interface systems and exchange data.

Implications:
• Significant energy and resources must be committed to this task. It is the key to improving the Oncology Informatics environment.
• A process must be developed to manage the data definitions within the RLS and the vocabularies it leverages.
• Ambiguities resulting from multiple parochial definitions of data must give way to accepted national or global definitions and understanding.
• Multiple data standardization initiatives need to be coordinated.
• Functional data administration responsibilities must be assigned.
• ASCO must seek to add to and inform data definitions within national vocabulary sets.

Principle 2: Data is an Asset

Statement:
Data is an asset that has value to the organization, its members, and RLS participants, and is managed accordingly.

Rationale:
Data is a valuable resource; it has a real and measurable value. Accurate, timely data is critical to improving the quality of care. Just as most corporate assets are carefully managed, data is no exception.

Implications:
• ASCO will manage data as an organizational asset.
• All participants will be educated about the relationship between the value of data, sharing of data, security of data, and accessibility to data.
The RLS Architecture Principles

Principle 3: Data Stewardship and Harmonization

Statement:
Data elements are managed by an overall steward accountable for data quality, standardization, and definition. Stewards must have the authority and means to manage the data model for which they are accountable. The ‘data steward’ might be an internal or external body.

Rationale:
One of the benefits of an architected environment is the ability to share data across a network or networks. As the degree of data sharing grows and entities rely upon common information, it becomes essential that only the data steward makes decisions about the content and management of the data model.

Implications:
• The data steward will be responsible for meeting quality requirements levied upon the data model.
• A open forum between HIT industry and data steward should decide on process changes.

The RLS Architecture Principles

Principle 4: Data Integrity

Statement:
Data integrity must be maintained and verified using a systematic and ongoing approach.

Rationale:
Data integrity is critical. Obsolete, incorrect, or inconsistent data could adversely impact downstream systems and decisions.

Implications:
• Data quality will need to be measured and steps taken to improve data quality. Quality control measures must be implemented to ensure the integrity of the data.
• Procedures must be developed and used to prevent and correct errors in the information and to improve those processes that produce flawed information.
• It is essential that ASCO has the ability to provide user confidence in the data.
• It is essential to identify the true source of the data. Information should be captured electronically once and immediately validated as close to the source as possible.
The RLS Architecture Principles

Principle 5: Data Security and Access

Statement:
Data is protected from unauthorized use and disclosure. In addition to the traditional aspects of HIPAA, this includes, but is not limited to, protection of sensitive and proprietary information. Appropriate measures must be implemented to ensure that all access to data is monitored, controlled, and audited, while not inhibiting real-time access to data.

Rationale:
Ensuring the security and availability of data are often conflicting endeavors and too often lead to incompatible decisions. Open sharing of information must be balanced against the need to restrict the availability of protected health information, as well as proprietary and sensitive information. Confidence in ASCO's ability to secure data will be critical to the success of the RLS.

Implications:
• In order to adequately provide access to open information while maintaining secure information, security needs must be identified and developed at the data element level, not the application level.
• Security must be designed into data elements from the beginning; it cannot be added later.
• Systems, data, and technologies must be protected from unauthorized access and manipulation and safeguarded against inadvertent or unauthorized alteration, sabotage, disaster, or disclosure.

The RLS Architecture Principles

Principle 6: Openness means interoperability

Statement:
The success of the RLS depends on the interoperability of systems. Internally, we can dictate what the IT infrastructure will be. Externally, we cannot. The RLS must leverage standards and common frameworks.

Rationale:
Maximum capability must be realized by not adopting the least common denominators in technology and standards. Standards help ensure consistency, improve the ability to manage systems, improve user satisfaction, and protect IT investments, thus maximizing return on investment and reducing costs. Standards for interoperability help ensure support from multiple vendors for their products, and facilitate integration.

Implications:
• Interoperability standards and industry standards will be followed unless there is a compelling business reason to implement a non-standard solution.
• ASCO will leverage the experience of the RLS development to contribute to national interoperability standards setting initiatives.
• A process for setting standards, reviewing and revising them periodically, and granting exceptions must be established.
• Existing technology and standards must be identified and the analysis and evaluation documented.
The RLS Architecture Principles

Principle 7: Technology will be scalable and flexible

Statement:
The IT infrastructure should provide for as much flexibility and scalability as possible. Where underlying technology must change to support new business initiatives, those components must be isolated from the rest of the system. The underlying technical infrastructure must be scalable by either adding components or by replacing certain components with large or smaller scale components. Components should allow for a wide variety of configurations.

Rationale:
A scalable and flexible environment enhances responsiveness by minimizing the impact of change and allows for the most cost-effective platform to be deployed.

Implications:
• ASCO must seek technology infrastructure solutions for RLS development and expansion that maximize scalability and flexibility.

The RLS Architecture Principles

Principle 8: Systems should be autonomous

Statement:
A failure in one system must not adversely affect other systems.

Rationale:
Quality of service must be maintained to all users. Fail-safes must be implemented to minimize the scope of a disaster to a level more easily dealt with by operational staff.

Implications:
• ASCO must seek autonomous technology infrastructure solutions for RLS development and expansion.
The RLS Architecture Principles

Principle 9: Buy before build

Statement:
If at all possible, IT components should be purchased rather than custom built.

Rationale:
A quick time to market for the RLS is needed. Minimizing risks associated with custom development, especially those related to the support and maintenance of components.

Implications:
• Integration and operational risks may increase

The RLS Architecture Principles

Principle 10: Requirements-Based Change

Statement:
Changes to applications and technology are made only in response to organizational requests and/or changes in need.

Rationale:
This principle will foster an atmosphere where the information environment changes only in response to the needs of the organization and its users. This is to ensure that the purpose of the information support - the transaction of business - is the basis for any proposed change. Unintended effects on operations due to IT changes will be minimized.

Implications:
• Changes in implementation will only follow full examination of the proposed changes using the architecture models.
• We do not fund a technical improvement or system development unless a documented business need exists.
• Change management processes conforming to this principle will be developed and implemented.
• This principle may bump up against the responsive change principle. We must ensure the requirements documentation process does not hinder responsive change to meet legitimate organizational needs.
The RLS Architecture Principles

Principle 11: Responsive Change Management

Statement:
When the organization's needs dictate changes to the RLS environment, those changes are implemented in a timely manner.

Rationale:
The system must be responsive to the organization's needs and changes requested and approved by the organization must be implemented without unnecessary delay.

Implications:
• We have to develop processes for managing and implementing change that do not create delays.
• Users must be able to petition for changes, and have the ability to connect with a "business expert" to facilitate explanation and implementation of that need.
• If we are going to make changes, we must keep all system architecture plans, data definitions, integration documents, and all other related bodies updated.
• Adopting this principle might require additional resources.
• This may conflict with other principles.

Building the Use Cases

• Starting with high-level Patient & MD scenarios, followed by high-level functional business scenarios
• Iterative process
  – Each iteration goes a little deeper
  – Some architectural artifacts have emerged already
Prior to coming to the office, Dr. Smith’s practice creates a basic record for Ms. Jones. Her surgeon, Dr. Reyes, triggered this by sending a referral, as well as the path/labs/radiology/op notes, electronically.

Ms. Jones calls to schedule her first appointment with Dr. Smith.
3. During the first visit, Ms. Jones fills out the intake form. Dr. Smith accesses Ms. Jones’ record in the EHR and completes the H&P. Although Dr. Smith is working exclusively within his EHR system, the fact that this is a new patient visit can generate the population of a basic patient record in the RLS. In addition, Ms. Jones can later opt in/out of sharing her data via a patient portal.

4. Immediately following her first visit, an invitation can be sent to Ms. Jones home email automatically. She can use the invite to view/modify settings related to the sharing of her data.
To Ms. Jones, sharing means…

- she receives the latest educational content from both ASCO and ASCO affiliates
- information about the association of familial breast cancer with some genes and a suggestion that she discusses this with her oncologist
- secure messaging with her physicians
- direct access to her treatment plan and other clinical records

Chemotherapy Starts

5. Ms. Jones is now coming in for chemotherapy. As orders are written and administered, the data moves to ASCO.
Chemotherapy Starts

6. Ms. Jones uses the patient portal to monitor her symptoms and issues during treatment. She reports that she is having a lot of vomiting during cycle 2 of her AC, which triggers an alert to Ms. Jones to contact Dr. Smith’s office. Ms. Jones’ vomiting also is prioritized on the triage dashboard, monitored by a nurse in Dr. Smith’s office. Dr. Smith’s doctor makes a corrective change to her treatment protocol.

7. A nurse follows up with Ms. Jones via phone to check on her. Dr. Smith messages Ms. Jones and her care team about the treatment change, and we show that this course correction worked and potentially deflected a hospital readmission or adverse clinical event.
8. Ms. Jones comes in for an office visit at the end of her chemotherapy treatment. The system reminds Dr. Smith to discuss genetic testing and radiation therapy with Ms. Jones.

9. At the end of her treatment Dr. Smith generates a Treatment Summary and Survivorship Plan automatically using the system.
Chemotherapy Ends

10. The Treatment Summary and Survivorship Plan, continued reminders, and patient-specific content are automatically made available to Ms. Jones via the patient portal.
Conceptual Diagram of Artifacts

High-Level Components List

- **Infrastructure:**
  - Scalable Service Bus (possibly cloud-based)
  - Cloud-based logic engine
  - Data warehouse
  - Web Portal
  - Analytics and Reporting Tool(s)

- **Data:**
  - Well defined vocabularies/data elements
  - Standardization

*No tools/platforms/vocabularies/etc. have been chosen yet.*
Expected Hurdles...

• Lack of standardization
• EHR vendor engagement
• Data privacy and security
  – Legal and Technology
• Paradigm shifting in medical practice

Summary

• The RLS will be built in stages
  – Breast Cancer Pilot
• ASCO is the organization to take on this task
• The RLS has the ability to revolutionize the practice of oncology for all stakeholders