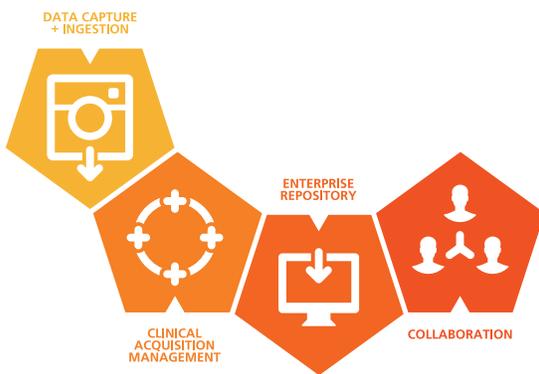# Functional Requirements for Enterprise Clinical Data Management: Solving Technical Problems, Satisfying User Needs

All around the world, regulatory requirements and market forces are driving a growing demand for higher-quality, more-efficient healthcare – supported by integrated IT systems that better serve the needs of every stakeholder. Healthcare IT managers are looking for innovative ways to reduce costs and increase operational efficiency across the healthcare system – not just at the departmental level. They're also looking to offer better support for the organization's core mission to provide multidisciplinary care of the highest quality.

As healthcare organizations plan for the future growth and integration of clinical data into their IT ecosystems, it's crucial to clearly define the functional requirements spanning the needs of users across the enterprise. This white paper provides an overview of the key functional requirements that must be built around four distinct modules:

- Data ingestion and capture
- Clinical acquisition management
- Enterprise repository
- Collaboration

When the requirements for each of these modules are met, everyone in the enterprise can work together – without barriers – to cost-effectively deliver the highest standard of care.

Why Defining Functional Requirements Matters

Well-defined functional requirements specify exactly what IT systems need to accomplish in each department and across the healthcare organization, and delineate specific metrics for success.

If the organization is drafting a request for proposal (RFP), functional requirements help frame the core questions posed in the RFP. If the organization already has one or more preferred vendors, functional requirements define the capabilities that must be provided to advance interoperability and accessibility. And if the organization wants to plan for growth and change, functional requirements define the standards that must be met to ensure future compatibility and minimize disruption.

Healthcare enterprises that have built departmental, EMR/EHR, administrative and other systems on an as-needed basis over many years may not have a consistent, overarching view of the entire ecosystem. The process of developing functional requirements brings clarity to an enterprise's current capabilities and provides a roadmap for optimizing them with each new IT investment.

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CLINICAL ACQUISITION MANAGEMENT
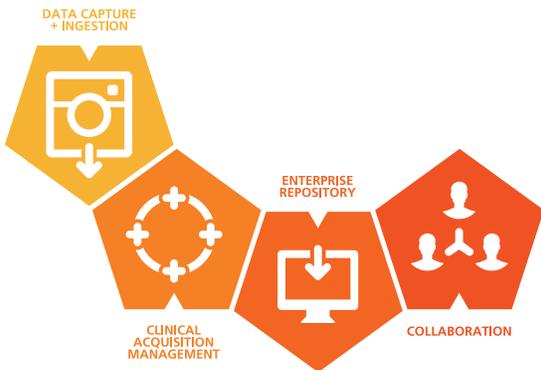
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Through the process of developing functional requirements, stakeholders gain insight into the workflow needs of various clinical service lines such as radiology, cardiology, dermatology, endoscopy, orthopaedics and so on. They identify the capabilities and limitations of existing systems, and the areas where customization, integration or possibly replacement will be required to optimize systems for clinical data management. And they can begin work on building a unified, patient-centered view of clinical information to support higher-quality, more efficient care.

Those are just a few reasons why developing a complete set of functional requirements is important. By going through the exercise of developing functional requirements, healthcare organizations can fully understand where they are today, where they want to go tomorrow and what it will take to get there.

Who Needs to Be Involved

Everyone in the organization who has a stake in the quality, integration and availability of clinical information – or in the technologies needed to capture, manage, store and deliver it – should have representation on the team tasked with developing functional requirements. This typically includes:

- The CIO or CMIO, who has primary responsibility for ensuring IT solutions throughout the enterprise are efficient, effective and well-integrated.

- The IT staff, including medical engineers charged with managing and optimizing specific equipment and processes.

- C-level leadership, such as the CEO, CFO and COO, who are responsible for approving IT projects and purchases.

- Departmental specialists, technicians and staff who can provide input on their workflow requirements as well as the interactions with other departments needed to support integrated clinical pathways for effective, multidisciplinary care.

- End users – including physicians, nurses, administrators, payers and patient representatives – who need access to clinical images for any purpose and can act as advocates for their specific access and contextual needs. Although these are not the ultimate decision-makers, they are key end users. The system that best meets their day-to-day needs will likely provide the greatest payback by supporting more efficient, effective healthcare delivery.

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Exploring the Four Crucial Modules

Again, functional requirements should be developed around these four modules:

1. Data Capture and Ingestion: Efficient acquisition of clinical images and documents

2. Clinical Acquisition Management: Providing data with a meaningful context for searching and interpretation

3. Archive: Appropriate storage of the data at each stage of its useful life

4. Collaboration: Data sharing, reporting and analysis to suit the needs of multidisciplinary teams as well as individual stakeholders

Here's a high-level look at the functional requirements that should be defined for each of these four modules.

Module 1: Data Capture and Ingestion

Defining functional requirements begins with asking the right questions. While the following list is not comprehensive, the requirements for data capture and ingestion are based on a discovery process that begins with questions such as:

*   How are images currently being acquired by each department? What devices are being used? What image formats do they produce – for example, JPG, MOV, MP4, PDF, CCD or ECG? What departmental standards are in place, if any, for distributing and viewing images? Does the department use the DICOM standard, a non-DICOM method such as ODF, or view images only within the department on dedicated equipment?

*   Outside of imaging departments, what other methods are being used to capture clinically relevant images? For example, are doctors using smartphone or tablet cameras and accessories (such as a microscope adapter) to capture images in remote and rural locations? How are the images analyzed? Is there a system in place for storing these images alongside clinical images from traditional departments and associating all images with the correct patient?

*   What are the workflows defined for each department to schedule appointments and exams, capture images, attach clinical notes, associate clinical data with the patient record and ingest the information into departmental and/or enterprise archiving systems?

*   In departments where workflows are inconsistent or possibly nonexistent, how can standardized workflows be developed that will serve the department's needs? What information and processes need to be captured on each department's worklists?

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- If clinical data is being stored locally or managed in a nonstandard way, what protocols need to be implemented to allow for centralized storage and management? How can legacy, proprietary as well as unstructured data be converted for storage and access using standard formats and protocols?

- Are there physical images and documents that need to be digitized and imported into the system? What processes are in place, or need to be developed, for doing this in a standardized way?

Based on the answers to questions like these, healthcare organizations can develop a set of functional requirements that clarify how different devices and workflows should be fine-tuned and harmonized to allow for efficient capture and ingestion of data within a central clinical records system – while preserving departmental autonomy.

Functional requirements for the first module primarily serve the needs of IT managers tasked with managing the connections used to inject clinical data into a centralized system – even when the data is being captured by departments that do not currently manage it in a standardized way. Although IT is the primary beneficiary of this module, department heads and staff are also crucial stakeholders, since the decisions made here will affect the workflows they use.

Module 2: Clinical Acquisition Management

As clinical images, documents and other data are acquired and ingested into the system, there needs to be a way to consistently provide the data with a meaningful context to make it searchable and assist in appropriate interpretation for various types of users. Some of the questions to ask in formulating requirements for clinical acquisition management include:

- How are clinical images, physician notes and other related data from each departmental source associated with a unique patient record? Do records need to be integrated with a Master Patient Index (MPI)? Which departments make this association as part of a well-defined workflow, and which do not? Is there a need to integrate with IHE-XDS workflow? Where do technologies and processes need to be implemented to ensure these linkages?

- Who are the key stakeholders who will need to search for and interpret clinical data for their specific purposes – for example, individual physicians, multidisciplinary care teams, hospital administrators, researchers, payers and patients? What kinds of images does each user group need to see, how can they efficiently search for images, and what contextual information needs to be provided to help them interpret and use clinical data appropriately for their individual needs?

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- What facilities and functions need to be served? For example, do telemedicine services require the provision of images with additional context to facilitate correct interpretation, such as indicating the body location of a close-up dermatology image? Is there contextual information that should be required to assist payers in determining reimbursements efficiently?

- What are the important details to capture about the patient, the exam, the image-capture equipment and settings, the image format and the clinical features of the image itself?

- What types of information might be superfluous or add little value and could therefore be excluded from the image context?

These questions guide the development of functional requirements for the contextual data that accompanies various types of clinical images – including whether each data item is required or optional, whether it is structured or unstructured, its format, and so on. Because these decisions affect departmental workflows, as well as the searchability and usability of clinical information, key stakeholders for this module include representatives of each department and each user group as well as IT managers.

For more detail on evaluating the levels, types and formats of contextual data that may be required, refer to our white paper, "Metadata: Creating Meaningful Access to Clinical Images and Data for Any User."

Module 3: Archive

To enable cross-enterprise collaboration around clinical images, healthcare organizations need to implement a central, vendor-neutral archive (VNA) to complement or replace department-specific and often proprietary picture archiving and communication systems (PACS). These are some of the questions that should be addressed in developing functional requirements for the VNA:

- What are the needs for interoperability? How will systems from multiple departments and vendors be accommodated to enable centralized archiving of clinical images and data? What imaging standards, communication protocols and adapters need to be supported? See our white paper, "Interoperability: Connecting the Healthcare Enterprise to Deliver Responsive Patient Care," for a more detailed discussion.

- How will data be migrated from older systems to the new archive? And if the archive is replaced by another vendor's system at some point in the future, how will the data be migrated and accessed? Is the system open and standards-based, so that existing databases can be used, or will time-consuming and expensive data conversions be required?

- What are the requirements for flexibility and scalability? Will the archive easily accommodate changes in the environment, such as migrating data to

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different storage platforms or adding new imaging modalities? Will it accommodate production growth as well as new expansions, mergers, acquisitions and partnerships?

- What are the needs for system availability, backups and disaster recovery? What measures need to be in place – such as redundant and offsite storage – to ensure data is always safeguarded and available to support critical workflows?

- What are the requirements for managing clinical data over its lifecycle – from when the image is first archived during an episode of care, through diagnosis and treatment, to medium- and long-term storage as part of a longitudinal patient record? What is the appropriate balance at each stage between quick access and affordable storage space? Will different storage tiers be structured around different models, such as enterprise-owned, remotely managed or cloud-based storage services?

- How will data quality and consistency be ensured? Will the VNA be required to perform tag morphing when legacy data and connected systems do not provide fully compliant HL7/DICOM transactions? How will data from every source be normalized and tagged for sharing with other systems? How will non-DICOM, unstructured data and proprietary formats be handled?

- Will ownership of data remain with the source system, with any changes made there captured reliably in the archive? How can data conflicts be avoided and managed? How will patients be consistently matched when they may have been assigned multiple IDs over different episodes and locations of care?

- How will the VNA provide for security and patient privacy? How will access control be defined for various user groups and data sets? What authentication standards and procedures will be used? How will communication channels be secured? Will anonymization be required, for example when sharing data externally for research purposes? What reports will be required for audits and how will they be made available?

These are some of the core questions to ask in order to bring functional requirements for the VNA into focus. There are many more areas to explore about the capture workflow, quality control and metadata management, reporting for various purposes, device-independent viewing, usability factors for each user group and other issues. Because functional requirements for the VNA must address such a wide range of needs, virtually every type of stakeholder should be represented in the decision-making process.

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Module 4: Collaboration: Data Sharing, Reporting and Analysis

With the fourth module, we come to the ultimate purpose of an enterprise-wide clinical information management system: Providing the right images and documents to the right people when and where they need them, in a context and format they can use to help deliver more efficient, higher-quality care. The first three modules all support this goal, but functional requirements still need to be developed to specify how clinical information will be accessed and viewed. Examples of key questions to ask include:

- Who are all the user groups that will need access to clinical data and reports, and what are their specific format and presentation requirements? For example, what do various types of clinicians need to see versus the information required by administrators, payers, patients and other user groups? What are the requirements for clinical versus business- or system-oriented data?

- What types of information need to be available in real time to aid business decision-making, and what types can be mineable for ongoing monitoring on a monthly, quarterly or yearly basis? For example, what are the accessibility needs for information such as patient wait time versus quality reports for reimbursement?

- How can all the data formats in the VNA and all the presentation formats required by different user groups be accommodated? Which users and applications can be served by a general-purpose universal viewer, and what department- and applications-specific viewers also need to be supported? How can the most users be accommodated without unnecessary disruption and investment?

- If Web-based technology is used as a universal method to distribute and view clinical data, what security policies and access controls will be required? Will doctors, patients or other users be permitted to download, print and share information more widely? What sharing is permitted per local privacy regulations, and how will the system enforce this?

- What rights do patients have to access their own information and permit or block other users who wish to see it? Will patients have the ability to upload their historical data so that, for example, a new doctor can review it prior to a scheduled appointment?

- Will views of clinical information be incorporated into the EMR/EHR system to allow a complete view of clinical images and documents alongside history, admitting, diagnostic, treatment and other patient information? How will this be accomplished? Will users be able to select a patient in the EMR/EHR and directly access workflows and clinical information from there?

- How will clinical workflows be supported? Will the entire pathway be captured and accessible from the beginning, with seamless updates as new

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information is captured and ingested for the patient? What different displays will be required, for example, to view pathways by date or by department?

- How will data enable new services for your organization – for example, to support patient transfers, offer second opinions, promote remote consultations, enable new telemedicine services to rural clinics, and so on?

- How will data be shared beyond the organization – for example, to support a regional healthcare system, an accountable care organization (ACO), or a population management program? If multiple organizations with their own managed archives need to collaborate, how will patient and clinical information be requested and shared?

- How will mobile devices be supported, controlled and secured? What capabilities will be permitted on enterprise-owned and personal devices? What applications will play a role, now or in the future, for various types of users?

While this list of questions is far from complete, the common theme for the collaboration module is serving the different needs of all users while ensuring the consistency, integrity and security of clinical data. Key stakeholders are user representatives, IT managers and C-level decision makers.

The Role of Carestream Health

Healthcare organizations – especially as they grow – have historically addressed IT issues as they arise using an available, targeted solution. Collaborative capabilities are structurally limited as departments and technologies have evolved in different ways, at different rates. The healthcare IT challenges of our time are to bridge diverse data formats, communication protocols and user needs to support collaborative efficiency and quality across the healthcare ecosystem.

Carestream specializes in helping organizations bring context, accessibility and relevance to their clinical data. We understand the role played by established standards such as IHE, HL7, FHIR, DICOM, XDS-I and others, as well as the need to bring nonstandard systems and data into the collaborative environment. Just as important, we understand the needs of clinicians, patients, administrators and other stakeholders – each seeking to contribute in their own way to better healthcare.

Our Clinical Collaboration Platform was developed to provide answers to the kinds of questions we've asked in this white paper – the questions you'll be asking as you develop functional requirements for your clinical information systems.

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We designed the Clinical Collaboration Platform with modules that can be used individually or together to address each of the four topics we've discussed here. Through our leadership in analyzing and addressing the functional requirements of the connected, collaborative healthcare enterprise, no one is better positioned to help you analyze your needs than Carestream Health.

Whether or not you are a current customer, whether or not you choose Carestream for your future needs, let us help you fine-tune and address your unique functional requirements.

To learn more and contact Carestream for a consultation, visit us at: www.carestream.com/collaboration

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Appendix: Checklist of System Requirements

	YES	NO
Module 1: Data Capture and Ingestion		
1. Capable of ingesting multiple data file types such as JPG, MOV, MP4, PDF, CCD, ECG, DICOM		
2. Capable of integrating diverse device sets, including smartphones and tablets		
3. Option to complement enterprise-wide scheduling to enable ad-hoc departmental scheduling		
4. Ability to attach clinical notes with exam		
5. Optional capture solution to integrate nonstandard devices		
6. Ability to convert legacy nonstandard data		
Module 2: Clinical Acquisition Management		
1. Ability to integrate with Enterprise Master Patient Index to ensure patient record integrity and maintain unique record		
2. Able to integrate with IHE-XDS workflow (registry, repository, consumer)		
3. Metadata tagging functionality to add clinical context based on type of modality or specialty so images are searchable		
4. Capable of dynamic, rules-based tag mapping/morphing and data reconciliation to normalize various data		
5. Allows users to easily access various capabilities from any Web-enabled device		
6. Interoperable with various standards such as HL7, DICOM, IHE, Web services (such as FHIR)		
7. Supports multiple patient ID lookup and reconciliation through standard eMPI or PIX		
8. Access to multiple file origins in order to import data		
Module 3: Archive		
1. Option to take over legacy archive without migration		
2. Migration capabilities		
3. Advanced image-data lifecycle management and multi-tier storage capabilities		
4. Built-in business continuity functionality		
5. Standards-based archive		
6. Various disaster recovery options		
7. Tag morphing capabilities to manage unstructured data or legacy archive that was in proprietary format		
8. Defined user-access control and permission tools		
9. Active system monitoring accessible from anywhere		
Module 4: Collaboration, Data Sharing, Reporting and Analysis		
1. User-aware viewer for physicians, patients and others		
2. FDA-cleared for clinical reading and mobile access to facilitate enterprise image access; for example, bedside consultation		
3. Real-time business dashboards with various key performance indicators available		
4. Zero-footprint viewers can be embedded in existing solutions, such as an EMR portal		
5. Physician viewer enables side-by-side comparison of multiple data types; provides ability to show attached reports		
6. Patient viewer enables patients to manage access rights		
7. Viewer is an XDS-I consumer and supports federated query from multiple sources for regional image exchange		
8. Viewer is vendor-neutral and complements existing departmental PACS		

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